UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the Fiscal Year Ended **December 31, 2022**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from _____ to _____

Commission File No. 001-14778

SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**41-1505029**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
29 EMMONS DRIVE, SUITE B-10 PRINCETON, NJ	**08540**
(Address of principal executive offices)	(Zip Code)

(609) 538-8200

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12 (b) of the Act:

Title of each class	**Trading Symbol (s)**	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	SNGX	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the common stock held by non-affiliates of the registrant was $25,734,915 (assuming, for this purpose, that executive officers, directors and holders of 10% or more of the common stock are affiliates), based on the closing price of the registrant's common stock as reported on The Nasdaq Capital Market on June 30, 2022.

On March 24, 2023, there were 2,924,491 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: None.

SOLIGENIX, INC.

ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2022

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that reflect our current expectations about our future results, performance, prospects and opportunities. These forward-looking statements are not guarantees of future performance and are subject to significant risks, uncertainties, assumptions and other factors, which are difficult to predict and may cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements. The forward-looking statements within this report may be identified by words such as “believes,” “anticipates,” “expects,” “intends,” “may,” “would,” “will” and other similar expressions. However, these words are not the exclusive means of identifying these statements. Statements that are not historical facts are based on our current expectations, beliefs, assumptions, estimates, forecasts and projections for our business and the industry and markets related to our business and are forward-looking statements.

Actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors which may affect these actual outcomes and results include, without limitation:

- uncertainty as to whether our product candidates will be sufficiently safe and effective to support regulatory approvals;
- uncertainty inherent in developing therapeutics and vaccines, and manufacturing and conducting preclinical and clinical trials;
- our ability to obtain future financing or funds when needed, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;
- that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;
- maintenance and progression of our business strategy;
- the possibility that our products under development may not gain market acceptance;
- our expectations about the potential market sizes and market participation potential for our product candidates may not be realized;
- our expected revenues (including sales, milestone payments and royalty revenues) from our product candidates and any related commercial agreements of ours may not be realized;
- the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner and the ability of such partners to timely address any regulatory issues that have arisen or may arise in the future;
- competition existing today or that may arise in the future, including the possibility that others may develop technologies or products superior to our products;
- our ability to comply with listing requirements and maintain the listing of our common stock on The Nasdaq Capital Market;
- the effect that global pathogens could have on financial markets, materials sourcing, service providers, patients, clinical study sites, governments and population (e.g. Coronavirus Disease 2019 (“COVID-19”)); and
- other factors, including those “Risk Factors” set forth under Part I, Item 1A. “Risk Factors” in this Annual Report.

Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances occurring subsequent to the filing of this Form 10-K with the United States (“U.S.”) Securities and Exchange Commission (“the SEC”) or for any other reason. You should carefully

review and consider the various disclosures we make in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Note Regarding Reverse Stock Split

On February 9, 2023, we completed a reverse stock split of our issued and outstanding shares of common stock at a ratio of one-for-fifteen, whereby, every fifteen shares of our issued and outstanding common stock was converted automatically into one issued and outstanding share of common stock without any change in the par value per share. No fractional shares were issued as a result of the reverse stock split. Any fractional shares that would otherwise have resulted from the reverse stock split were rounded up to the next whole number. Our common stock began trading on The NASDAQ Capital Market on a reverse split basis at the market opening on February 10, 2023. All share and per share data have been restated to reflect this reverse stock split.

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PART I

Item 1. Business

This Annual Report on Form 10-K contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this report that could cause actual results to differ materially from those indicated in any forward-looking statements, including those set forth in "Risk Factors" in this Annual Report on Form 10-K. See "Cautionary Note Regarding Forward Looking Statements."

Our Business Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: Specialized BioTherapeutics and Public Health Solutions.

Our Specialized BioTherapeutics business segment is developing and moving toward potential commercialization of HyBryte™ (a proposed proprietary name of SGX301 or synthetic hypericin), a novel photodynamic therapy ("PDT"), utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"). With a successful Phase 3 study completed, regulatory approval is being sought and commercialization activities for this product candidate are being advanced initially in the U.S. Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, our first-in-class innate defense regulator ("IDR") technology, dusquetide (SGX942) for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation including pediatric Crohn's disease (SGX203).

Our Public Health Solutions business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease and our vaccine programs targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases ("NIAID"), the Biomedical Advanced Research and Development Authority ("BARDA") and the Defense Threat Reduction Agency ("DTRA").

An outline of our business strategy follows:

- Following positive primary endpoint results for the Phase 3 FLASH (Florescent Light Activated Synthetic Hypericin) clinical trial of HyBryte™ in CTCL as well as further statistically significant improvement in response rates with longer treatment (18 weeks compared to 12 and 6 weeks of treatment), meet with the United States ("U.S.") Food and Drug Administration ("FDA") to discuss the contents of a refusal to file ("RTF") letter recently issued by the FDA in response to the HyBryte™ new drug application ("NDA") for the treatment of CTCL. We are preparing for a meeting, categorized as Type A, with the FDA to clarify and respond to the issues identified in the RTF letter and to seek additional guidance concerning information that the FDA would require for a resubmitted NDA to be deemed acceptable to file, in order to advance HyBryte™ towards marketing approval and U.S. commercialization while continuing to explore ex-U.S. partnership.

- Expanding development of synthetic hypericin under the research name SGX302 into psoriasis with the conduct of a Phase 2a clinical trial, following the positive Phase 3 FLASH study and positive proof-of-concept demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients.

- Following feedback from the United Kingdom ("UK") Medicines and Healthcare products Regulatory Agency ("MHRA") that a second Phase 3 clinical trial of SGX942 in the treatment of oral mucositis would be required to support a marketing authorization; design a second study and attempt to identify a potential partner(s) to continue this development program.

- Continue development of our therapeutic SGX943 and our heat stabilization platform technology, ThermoVax®, in combination with our programs for RiVax® (ricin toxin vaccine), CiVax™ (COVID-19 vaccine) and filovirus vaccines (targeting Ebola, Sudan, and Marburg viruses), with U.S. government funding support.

- Continue to apply for and secure additional government funding for each of our Specialized BioTherapeutics and Public Health Solutions programs through grants, contracts and/or procurements.

- Pursue business development opportunities for our pipeline programs, as well as explore all strategic alternatives, including but not limited to merger/acquisition strategies.

- Acquire or in-license new clinical-stage compounds for development, as well as evaluate new indications with existing pipeline compounds for development.

Corporate Information

We were incorporated in Delaware in 1987 under the name Biological Therapeutics, Inc. In 1987, we merged with Biological Therapeutics, Inc., a North Dakota corporation, pursuant to which we changed our name to “Immunotherapeutics, Inc.” We changed our name to “Endorex Corp.” in 1996, to “Endorex Corporation” in 1998, to “DOR BioPharma, Inc.” in 2001, and finally to “Soligenix, Inc.” in 2009. Our principal executive offices are located at 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Our Product Candidates in Development

The following tables summarize our product candidates under development:

Specialized BioTherapeutics Product Candidates*

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
HyBryte™	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate compared to placebo; Phase 3 trial completed; demonstrated statistical significance in primary endpoint in March 2020 (Cycle 1) and demonstrated continued improvement in treatment response with extended treatment in April 2020 (Cycle 2) and October 2020 (Cycle 3); NDA submitted December 2022; FDA RTF letter received February 2023; Prepare for Type A meeting with the FDA
SGX302	Mild-to-Moderate Psoriasis	Positive proof-of-concept demonstrated in a small Phase 1/2 pilot study; Phase 2a protocol and Investigation New Drug ("IND") clearance received from the FDA; Phase 2a study initiated December 2022
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial completed; demonstrated significant response compared to placebo with positive long-term (12 month) safety also reported; Phase 3 clinical trial results announced December 2020: the primary endpoint of median duration of severe oral mucositis ("SOM") did not achieve the pre-specified criterion for statistical significance ($p \leq 0.05$); although biological activity was observed with a 56% reduction in the median duration of SOM from 18 days in the placebo group to 8 days in the SGX942 treatment group; analyze full dataset from Phase 3 study and design a second Phase 3 clinical trial; continued development contingent upon identification of partnership
SGX203†	Pediatric Crohn's disease	Phase 1/2 clinical trial completed; efficacy data, pharmacokinetic(PK)/ pharmacodynamic (PD) profile and safety profile demonstrated; Phase 3 clinical trial initiation contingent upon additional funding, such as through partnership

Public Health Solutions*†

ThermoVax®	Thermostability of vaccines for Ricin toxin, Ebola, Marburg and SARS- CoV-2 (COVID-19) viruses	Pre-clinical
RiVax®	Vaccine against Ricin Toxin Poisoning	Phase 1a and 1b trials completed, safety and neutralizing antibodies for protection demonstrated; Phase 1c trial initiated December 2019, closed January 2020
SGX943	Therapeutic against Emerging Infectious Diseases	Pre-clinical
CiVax™	Vaccine against COVID-19	Pre-clinical

* *Timelines subject to potential disruption due to COVID-19 outbreak.*

† *Contingent upon continued government contract/grant funding or other funding source.*

Specialized BioTherapeutics Overview

Synthetic Hypericin

Synthetic Hypericin is a potent photosensitizer that is topically applied to skin lesions, taken up by cutaneous T-cells and then activated by safe visible light. Hypericin is also found in several species of Hypericum plants, although this active moiety is chemically synthesized by a proprietary manufacturing process and not extracted from plants. Importantly, hypericin is optimally activated with visible light thereby avoiding the negative consequences of ultraviolet ("UV") light. Other light therapies using UVA or UVB light can result in serious adverse effects including secondary skin cancers.

Combined with photoactivation, in clinical trials synthetic hypericin has demonstrated significant anti-proliferative effects on activated normal human lymphoid cells and inhibited growth of malignant T-cells isolated from CTCL patients. In both settings, it appears that the mode of action is an induction of cell death in a concentration as well as a light dose-dependent fashion. These effects appear to result, in part, from the generation of singlet oxygen during photoactivation of hypericin.

Synthetic hypericin is one of the most efficient known generators of singlet oxygen, the key component for phototherapy. The generation of singlet oxygen induces necrosis and apoptosis in adjacent cells. The use of topical synthetic hypericin coupled with directed visible light results in generation of singlet oxygen only at the treated site. We believe that the use of visible light (as opposed to cancer-causing UV light) is a major advance in photodynamic therapy. In a small published Phase 1/2 proof of concept pilot clinical study using synthetic hypericin twice weekly for six weeks, statistically significant efficacy was demonstrated in patients with CTCL (58.3% response, $p=0.04$) and psoriasis (80% response, $p<0.02$). Subsequently, a pivotal Phase 3 study in CTCL has further confirmed the biological efficacy of synthetic hypericin (termed HyBryte™ in the context of CTCL).

HyBryte™ – for Treating Cutaneous T-Cell Lymphoma

HyBryte™ is a novel, first-in-class, PDT, that utilizes safe visible light for activation. The active ingredient in HyBryte™ is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by visible fluorescent light 16 to 24 hours later.

Based on the positive and previously published Phase 1/2 results, we initiated our pivotal Phase 3 clinical study of HyBryte™ for the treatment of CTCL during December 2015 and completed the trial in 2020. This trial, referred to as the "FLASH" (Fluorescent Light Activated Synthetic Hypericin) study, aimed to evaluate the response to HyBryte™ as a skin directed therapy to treat early stage CTCL. We completed the study with approximately 35 CTCL centers across the U.S. participating in this pivotal trial. The Phase 3 protocol was a highly powered, double-blind, randomized, placebo-controlled, multicenter trial that enrolled 169 subjects (166 evaluable). The trial consisted of three treatment cycles, each of eight weeks duration. Treatments were administered twice weekly for the first six weeks and treatment response was determined at the end of the eighth week. In the first treatment cycle, approximately 66% of subjects received HyBryte™ and 33% received placebo

treatment of their index lesions. In the second cycle, all subjects received HyBryte™ treatment of their index lesions, and in the third cycle, all subjects received HyBryte™ treatment of all of their lesions. The majority of subjects enrolled elected to continue into the third optional, open-label cycle of the study. Subjects were followed for an additional six months after their last evaluation visit. The primary efficacy endpoint was assessed on the percentage of patients in each of the two treatment groups (i.e., HyBryte™ and placebo) achieving a partial or complete response of the treated lesions, defined as a ≥ 50% reduction in the total Composite Assessment of Index Lesion Disease Severity ("CAILS") score for three index lesions at the Cycle 1 evaluation visit (Week 8) compared to the total CAILS score at baseline. Secondary endpoints for the trial included the duration of responses, the extent of the regression of the tumors, and the safety of the treatment. We continue to work closely with the Cutaneous Lymphoma Foundation, as well as the National Organization for Rare Disorders.

Positive primary endpoint analysis for the Phase 3 study for HyBryte™ was completed in March 2020. The study enrolled 169 patients (166 evaluable) randomized 2:1 to receive either HyBryte™ (116 patients) or placebo (50 patients) and demonstrated a statistically significant treatment response ($p=0.04$) in the CAILS primary endpoint assessment at 8 weeks for Cycle 1. A total of 16% of the patients receiving HyBryte™ achieved at least a 50% reduction in their index lesions compared to only 4% of patients in the placebo group at 8 weeks. HyBryte™ treatment in the first cycle was safe and well tolerated.

Analysis of the second open-label treatment cycle (Cycle 2) was completed in April 2020, showing that continued treatment with HyBryte™ twice weekly for an additional 6 weeks (12 weeks total) increased the positive response rate to 40% ($p<0.0001$ compared to placebo and $p<0.0001$ compared to 6-weeks treatment). After the subsequent additional 6-week treatment, the response rate in patients receiving a total of 12 weeks treatment increased two and a half-fold. Treatment responses were assessed at Week 8 (after 6 weeks of treatment) and at Week 16 (after 12 weeks of treatment). A positive response was defined as an improvement of at least 50% in the CAILS score for the three index lesions evaluated in both Cycles 1 and 2. The data continued to indicate that HyBryte™ was safe and well tolerated.

Analysis of the optional third open-label treatment cycle (Cycle 3) was completed in October 2020. Cycle 3 was focused on safety and all patients could elect to receive HyBryte™ treatment of all their lesions for an additional 6 weeks or up to 18 weeks in total. Of note, 66% of patients elected to continue with this optional safety cycle of the study. Of the subset of patients that received HyBryte™ throughout all three cycles of treatment (18 weeks), 49% of them demonstrated a treatment response ($p=0.046$ vs. patients completing 12 weeks of HyBryte™ treatment in Cycle 2; $p<0.0001$ vs. patients receiving placebo in Cycle 1). Moreover, in a subset of patients evaluated in this cycle, it was demonstrated that HyBryte™ is not systemically available, consistent with the general safety of this topical product observed to date. At the end of Cycle 3, HyBryte™ continued to be well tolerated despite extended and increased use of the product to treat multiple lesions.

In addition, continued analysis of results from the protocol mandated efficacy cycles (Cycles 1 and 2) of the study revealed that 12 weeks of treatment (Cycle 2) with HyBryte™ is equally effective on both patch (response 37%, $p=0.0009$) and plaque (response 42%, $p<0.0001$) lesions when compared to Cycle 1 placebo lesion responses, further demonstrating the unique benefits of the more deeply penetrating visible light activation of hypericin.

HyBryte™ has received Orphan Drug designation as well as Fast Track designation from the FDA. The Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. In addition to providing a seven-year term of market exclusivity for HyBryte™ upon final FDA approval, Orphan Drug designation also positions us to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of FDA user fees for the potential submission of a NDA for HyBryte™, and certain tax credits. In addition, Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast Track designation is designed to facilitate the development and expedite the review of new drugs. For instance, we were eligible to submit an NDA for HyBryte™ on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review. HyBryte™ for the treatment of CTCL also was granted Orphan Drug designation from the European Medicines Agency ("EMA") Committee for Orphan Medical Products and Promising Innovative Medicine ("PIM") designation from the MHRA, as well as Innovation Passport under the Innovative Licensing and Access Pathway ("ILAP") in the UK.

During January 2021, we signed an exclusive Supply, Distribution and Services Agreement with The Daavlin Distributing Co. ("Daavlin"), securing long-term supply and distribution of a commercially ready light device, which is an integral component of the regulatory and commercial strategy for HyBryte™ for the treatment of CTCL. Pursuant to the agreement, Daavlin will exclusively manufacture the proprietary light device for use with HyBryte™ for the treatment of CTCL. Upon

approval of HyBryte™ by the FDA, we will promote HyBryte™ and the companion light device, and facilitate the direct purchase of the device from Daavlin. Daavlin will exclusively distribute and sell the HyBryte™ light device to us, physicians and patients.

In April 2021, the FDA conditionally accepted HyBryte™ as the proposed brand name for SGX301 or synthetic hypericin, in the treatment of early stage CTCL. The name HyBryte™ was developed in compliance with the FDA's *Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names*. The FDA's conditional approval validates HyBryte™ as a proprietary name that is consistent with the FDA's goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use. Final approval of the HyBryte™ proprietary name is conditioned on FDA approval of the product candidate, SGX301.

In May 2021, HyBryte™ was awarded an "Innovation Passport" for the treatment of early stage CTCL in adults under the UK's ILAP. The decision to award the Innovation Passport to the HyBryte™ program was made by the Innovative Licensing and Access Pathway Steering Group, which is comprised of representatives from MHRA, the National Institute for Health and Care Excellence ("NICE"), and the Scottish Medicines Consortium ("SMC"). ILAP was launched at the start of 2021 to accelerate the development and access to promising medicines, thereby facilitating patient access to new medicines. The pathway, part of the UK's plan to attract life sciences development in the post-Brexit era, features enhanced input and interactions with the MHRA, NICE, and SMC. The innovation passport designation is the first step in the ILAP process and triggers the MHRA and its partner agencies to create a target development profile to chart out a roadmap for regulatory and development milestones with the goal of early patient access in the UK. Other benefits of ILAP include a 150-day accelerated assessment, rolling review and a continuous benefit risk assessment.

As a result of discussions with the FDA regarding the HyBryte™ NDA submission and due to disruptions caused by the global COVID-19 pandemic resulting in delays by the commercial active pharmaceutical ingredient ("API") contract manufacturer affecting the timing of availability of the pre-requisite amount of accrued stability data required to file the NDA, we filed the NDA with the FDA in December of 2022. We did not pursue a rolling NDA submission, so that we could provide additional supportive data in the NDA filing.

In June 2021, we received a Paediatric Investigation Plan ("PIP") waiver from the EMA for HyBryte™. As part of the regulatory process for the registration of new medicines with the EMA, pharmaceutical companies are required to provide a PIP outlining their strategies for investigation of the new medicinal products in the pediatric population. In some instances, a waiver negating the need for a PIP for certain conditions may be granted by the EMA when development of a medicine for use in children is not feasible or appropriate, as is the case for HyBryte™ in CTCL which is extremely rare in children.

In September 2021, we were granted orphan drug designation for the active ingredient hypericin for the treatment of T-cell lymphoma, extending the target population beyond CTCL as previously granted by the FDA.

In July 2022, the results of our successful Phase 3 FLASH study evaluating HyBryte™ for the treatment of CTCL were published in the *Journal of the American Medical Association (JAMA) Dermatology*.

In July 2022, we received agreement from the FDA on an initial pediatric study plan (iPSP) for HyBryte™ for the treatment of CTCL. The agreed iPSP stipulates that we intend to request a full waiver of pediatric studies upon submission of the NDA. Agreement with FDA on an iPSP is one of the regulatory requirements that must be met prior to submitting a NDA.

In September 2022, the FDA awarded an Orphan Products Development grant to support the evaluation of HyBryte™ for expanded treatment in patients with early-stage CTCL. The grant, totaling $2.6 million over 4 years, was awarded to a prestigious academic institution that was a leading enroller in the recently published positive Phase 3 FLASH study in the treatment of early stage CTCL.

In December 2022, we submitted the HyBryte™ NDA for the treatment of CTCL with the FDA.

In February 2023 we received a RTF letter from the FDA for the HyBryte™ NDA. Upon preliminary review, the FDA determined that the NDA was not sufficiently complete to permit substantive review. We are preparing for a Type A meeting with the FDA to clarify and respond to the issues identified in the RTF letter and to seek additional guidance concerning information that the agency would require for a resubmitted NDA to be deemed acceptable.

We estimate the potential worldwide market for HyBryte™ is in excess of $250 million for the treatment of CTCL. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

Cutaneous T-Cell Lymphoma

CTCL is a class of non-Hodgkin's lymphoma ("NHL"), a type of cancer of the white blood cells that are an integral part of the immune system. Unlike most NHLs, which generally involve B-cell lymphocytes (involved in producing antibodies), CTCL is caused by an expansion of malignant T-cell lymphocytes (involved in cell-mediated immunity) normally programmed to migrate to the skin. These skin-trafficking malignant T-cells migrate to the skin, causing various lesions to appear that may change shape as the disease progresses, typically beginning as a rash and eventually forming plaques and tumors. Mycosis fungoides ("MF") is the most common form of CTCL. It generally presents with skin involvement only, manifested as scaly, erythematous patches. Advanced disease with diffuse lymph node and visceral organ involvement is usually associated with a poorer response rate to standard therapies. A relatively uncommon sub-group of CTCL patients present with extensive skin involvement and circulating malignant cerebriform T-cells, referred to as Sézary syndrome. These patients have substantially graver prognoses (expected five-year survival rate of 24%), than those with MF (expected five-year survival rate of 88%).

CTCL mortality is related to stage of disease, with median survival generally ranging from about 12 years in the early stages to only 2.5 years when the disease has advanced. There is currently no FDA-approved drug for front-line treatment of early stage CTCL. Treatment of early-stage disease generally involves skin-directed therapies. One of the most common unapproved therapies used for early-stage disease is oral 5 or 8-methoxypsoralen ("Psoralen") given with ultraviolet A ("UVA") light, referred to as PUVA, which is approved for dermatological conditions such as disabling psoriasis not adequately responsive to other forms of therapy, idiopathic vitiligo and skin manifestations of CTCL in persons who have not been responsive to other forms of treatment. Psoralen is a mutagenic chemical that interferes with DNA causing mutations and other malignancies. Moreover, UVA is a carcinogenic light source that when combined with the Psoralen, results in serious adverse effects including secondary skin cancers; therefore, the FDA requires a Black Box warning for PUVA.

CTCL constitutes a rare group of NHLs, occurring in about 4% of the approximate 500,000 individuals living with NHL. We estimate, based upon review of historic published studies and reports and an interpolation of data on the incidence of CTCL, that it affects over 20,000 individuals in the U.S., with approximately 2,800 new cases seen annually.

SGX302 – for Treating Mild-to-Moderate Psoriasis

SGX302 (synthetic hypericin) is a potent photosensitizer that is topically applied to skin lesions and taken up by cutaneous T-cells. With subsequent activation by safe, visible light, T-cell apoptosis is induced, addressing the root cause of psoriasis lesions. Other PDTs have shown efficacy in psoriasis with a similar apoptotic mechanism, albeit using UV light associated with more severe potential long-term toxicities. The use of visible light in the red-yellow spectrum has the advantage of deeper penetration into the skin (much more than UV light) potentially treating deeper skin disease and thicker plaques and lesions, similar to what was observed in the positive Phase 3 FLASH study in CTCL. Further, this treatment approach avoids the risk of secondary malignancies (including melanoma) inherent with both the frequently used DNA-damaging drugs and other phototherapies that are dependent on UVA or UVB exposure. The use of SGX302 coupled with safe, visible light also avoids the risk of serious infections and cancer associated with the systemic immunosuppressive treatments used in psoriasis.

In September 2021, following the validation of synthetic hypericin's biologic activity in the positive pivotal Phase 3 FLASH study in CTCL, as well as positive proof-of-concept demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients, we decided to expand this novel therapy into a Phase 2a clinical trial in mild-to-moderate psoriasis. We estimate the potential worldwide market for SGX302 to be in excess of $1 billion for the treatment of mild-to-moderate psoriasis. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

In June 2022, we received FDA IND clearance for our Phase 2a clinical trial (protocol number HPN-PSR-01) titled, "*Phase 2 Study Evaluating SGX302 in the Treatment of Mild-to-Moderate Psoriasis*." In December 2022, we initiated patient

enrollment for the Phase 2a study (protocol number HPN-PSR-01) evaluating SGX302 in the treatment of mild-to-moderate psoriasis. The Phase 2a clinical trial (protocol number HPN-PSR-01) will target enrollment of up to 42 patients ages 18 years or older with mild to moderate, stable psoriasis covering 2 to 30% of the body. In both Parts A and B, all patients will apply the study drug twice per week and activate the drug with visible light 24 ± 6 hours later using the supplied visible light devices and according to the manufacturer's instructions. Patients will undergo treatments for a total of 18 weeks and, on completion, will be followed for a four-week follow-up period in which patients will not receive other psoriasis treatments. In Part A, five to ten patients will be assigned open-label SGX302 (0.25% hypericin) at the time of enrollment. Once the tolerability and response to SGX302 has been established, Part B of the protocol will commence. In Part B, patients will be randomized to double-blind treatment groups at a ratio 1:1 of active drug to placebo ointment. Active dermatologic assessment of treated lesions for adverse events will be performed immediately before and during light treatments. Patients will be assessed for overall disease status through four weeks of follow-up. Efficacy endpoints will include the extent of lesion clearance and patient reported quality of life indices. Routine safety data also will be collected.

Psoriasis

Psoriasis is a chronic, non-communicable, itchy and often painful inflammatory skin condition for which there is no cure. Psoriasis has a significantly detrimental impact on patients' quality of life, and is associated with cardiovascular, arthritic, and metabolic diseases, as well as psychological conditions such as anxiety, depression and suicide. Many factors contribute to development of psoriasis including both genetic and environmental factors (e.g., skin trauma, infections, and medications). The lesions develop because of rapidly proliferating skin cells, driven by autoimmune T-cell mediated inflammation. Of the various types of psoriasis, plaque psoriasis is the most common and is characterized by dry, red raised plaques that are covered by silvery-white scales occurring most commonly on the elbows, knees, scalp, and lower back. Approximately 80% of patients have mild-to-moderate disease. Mild psoriasis is generally characterized by the involvement of less than 3% of the body surface area (“BSA”), while moderate psoriasis will typically involve 3-10% BSA and severe psoriasis greater than 10% BSA. Between 20% and 30% of individuals with psoriasis will go on to develop chronic, inflammatory arthritis (psoriatic arthritis) that can lead to joint deformations and disability. Studies have also associated psoriasis, and particularly severe psoriasis, with an increased relative risk of lymphoma, particularly CTCL. Although psoriasis can occur at any age, most patients present with the condition before age 35.

Treatment of psoriasis is based on its severity at the time of presentation with the goal of controlling symptoms. It varies from topical options including PDT to reduce pain and itching, and potentially reduce the inflammation driving plaque formation, to systemic treatments for more severe disease. Most common systemic treatments and even current topical photo/photodynamic therapy such as UV A and B, carry a risk of increased skin cancer.

Psoriasis is the most common immune-mediated inflammatory skin disease. According to the World Health Organization (“WHO”) Global Report on Psoriasis 2016, the prevalence of psoriasis is between 1.5% and 5% in most developed countries, with some suggestions of incidence increasing with time. It is estimated, based upon review of historic published studies and reports and an interpolation of data that psoriasis affects 3% of the U.S. population or more than 7.5 million people. Current estimates have as many as 60-125 million people worldwide living with the condition. The global psoriasis treatment market was valued at approximately $15 billion in 2020 and is projected to reach as much as $40 billion by 2027.

Dusquetide

Dusquetide (research name: SGX94) is an IDR that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing. Dusquetide is based on a new class of short, synthetic peptides known as IDRs. It has a novel mechanism of action in that it modulates the body’s reaction to both injury and infection and is both simultaneously anti-inflammatory and anti-infective. IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy. IDRs represent a novel approach to the control of infection and tissue damage via highly selective binding to an intracellular adaptor protein, sequestosome-1, also known as p62, which has a pivotal function in signal transduction during activation and control of the innate defense system. Preclinical data indicate that IDRs may be active in models of a wide range of therapeutic indications including life-threatening bacterial infections as well as the severe side-effects of chemo- and radiation-therapy. Additionally, due to selective binding to p62, dusquetide may have potential anti-tumor action.

Dusquetide has demonstrated efficacy in numerous animal disease models including mucositis, oncology, colitis, skin infection and other bacterial infections and has been evaluated in a double-blind, placebo-controlled Phase 1 clinical trial in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. Dusquetide was shown to have a good safety profile and be well-tolerated in all dose groups when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. We believe that market opportunities for dusquetide include, but are not limited to, oral and gastrointestinal mucositis, oncology (e.g., breast cancer), acute Gram-positive bacterial infections (e.g., methicillin resistant *Staphylococcus aureus* ("MRSA")), acute Gram-negative infections (e.g., acinetobacter, melioidosis), and acute radiation syndrome.

SGX942 – for Treating Oral Mucositis in Head and Neck Cancer

SGX942 is our product candidate containing our IDR technology, dusquetide, targeting the treatment of oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, we received Fast Track designation for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients from the FDA. In addition, dusquetide has been granted PIM designation in the UK by the MHRA for the treatment of SOM in head and neck cancer patients receiving chemoradiation therapy.

We initiated a Phase 2 clinical study of SGX942 for the treatment of oral mucositis in head and neck cancer patients in December of 2013. We completed enrollment in this trial and released positive results in December 2015. In this Phase 2 proof-of-concept clinical study that enrolled 111 patients, SGX942, at a dose of 1.5 mg/kg, successfully reduced the median duration of SOM by 50%, from 18 days to 9 days ($p=0.099$) in all patients and by 67%, from 30 days to 10 days ($p=0.040$) in patients receiving the most aggressive chemoradiation therapy for treatment of their head and neck cancer. The p-values met the prospectively defined statistical threshold of $p<0.1$ in the study protocol. A less severe occurrence of oral mucositis, ulcerative oral mucositis (defined as oral mucositis with a WHO score ≥2 corresponding to the occurrence of overt ulceration in the mouth), was also monitored during the study. In the patients receiving the most aggressive chemoradiation therapy, the median duration of oral mucositis was found to decrease from 65 days in the placebo treated patients to 51 days in the patients treated with SGX942 1.5 mg/kg ($p=0.099$).

In addition to identifying the best dose of 1.5 mg/kg, this study achieved all objectives, including increased incidence of "complete response" of tumor at the one month follow-up visit (47% in placebo vs. 63% in SGX942 at 1.5 mg/kg). Decreases in mortality and decreases in infection rate were also observed with SGX942 treatment, consistent with the preclinical results observed in animal models. Data from this Phase 2 trial are published in the Journal of Biotechnology.

SGX942 was found to be generally safe and well tolerated, consistent with the safety profile observed in the prior Phase 1 study conducted in 84 healthy volunteers. The long-term (12 month) follow-up data was consistent with the preliminary positive safety and efficacy findings. While the placebo population experienced the expected 12-month survival rate of approximately 80%, as defined in the Surveillance, Epidemiology, and End Results statistics 1975-2012 from the National Cancer Institute, the SGX942 1.5 mg/kg treatment group reported a 12-month survival rate of 93% (7% mortality in the SGX942 1.5 mg/kg group compared to 19% in the placebo group). Similarly, tumor resolution (complete response) at 12 months was better in the SGX942 1.5 mg/kg treatment group relative to the placebo population (80% in the 1.5 mg/kg group compared to 74% in the placebo group). The long-term follow-up results from the Phase 2 study are published in Biotechnology Reports.

In September 2016, we and SciClone Pharmaceuticals, Inc. ("SciClone") entered into an exclusive license agreement, pursuant to which we granted rights to SciClone to develop, promote, market, distribute and sell SGX942 in defined territories. Under the terms of the license agreement, SciClone will be responsible for all aspects of development, product registration and commercialization in the territories, having access to data generated by us. In exchange for exclusive rights, SciClone will pay us royalties on net sales, and we will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights.

Based on the positive and previously published Phase 2 results (Study IDR-OM-01), in July 2017, we initiated a pivotal Phase 3 clinical trial referred to as the "DOM–INNATE" (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) study. Approximately 50 U.S. and European oncology centers participated in this trial. The Phase 3 protocol (Study IDR-OM-02) was a highly powered, double-blind, randomized, placebo-controlled, multinational trial that sought to enroll approximately 260 subjects with squamous cell carcinoma of the oral cavity and oropharynx who were scheduled to receive a minimum total cumulative radiation dose of 55 Gy fractionated as 2.0-2.2 Gy per day with concomitant cisplatin

chemotherapy given as a dose of 80-100 mg/m^2 every third week. Subjects were randomized to receive either 1.5 mg/kg SGX942 or placebo given twice a week during and for two weeks following completion of chemoradiation therapy ("CRT"). The primary endpoint for the study was the median duration of SOM, which was assessed by oral examination at each treatment visit and then through six weeks following completion of CRT. Oral mucositis is evaluated using the WHO Grading system. SOM is defined as a WHO Grade of ≥3. Subjects are followed for an additional 12 months after the completion of treatment.

In April 2019, the Paediatric Committee of the EMA approved our PIP for SGX942, a prerequisite for filing a Marketing Authorization Application ("MAA") for any new medicinal product in Europe. The EMA also agreed that we may defer conducting the PIP until successful completion of our ongoing pivotal Phase 3 clinical trial of SGX942, which allows us to file the adult indication MAA prior to completion of the PIP.

In June 2020, the pivotal Phase 3 DOM–INNATE study (Study IDR-OM-02) completed enrollment of 268 subjects. In December 2020, the results of our Phase 3 clinical trial for SGX942 showed that the primary endpoint of median duration of SOM did not achieve the pre-specified criterion for statistical significance ($p \leq 0.05$); although biological activity was observed with a 56% reduction in the median duration of SOM from 18 days in the placebo group to 8 days in the SGX942 treatment group. Despite this clinically meaningful improvement, the variability in the distribution of the data yielded a p-value that was not statistically significant. Other secondary endpoints supported the biological activity of dusquetide, including a statistically significant 50% reduction in the median duration of SOM in the per-protocol population, which decreased from 18 days in the placebo group to 9 days in the SGX942 treatment group ($p=0.049$), consistent with the findings in the Phase 2 trial (Study IDR-OM-01). Similarly, incidence of SOM also followed this biological trend as seen in the Phase 2 study, decreasing by 16% in the SGX942 treatment group relative to the placebo group in the per-protocol population. The per-protocol population was defined as the population receiving a minimum of 55 Gy radiation and at least 10 doses of study drug (placebo or SGX942) throughout the intended treatment period, with no major protocol deviations (e.g. breaks in study drug administration longer than 8 days between successive doses).

Following analysis of the full dataset, including the 12-month long-term follow-up safety data in late 2021, we held a meeting with the MHRA to review the study results and to obtain further clarity on the future of the oral mucositis development program. The meeting was informative with the outcome being that based on the SGX942 biologic activity observed and the consistency in response between the Phase 2 and Phase 3 trials, the Phase 3 DOM-INNATE study could serve as the first of two Phase 3 studies required to support potential marketing authorization, assuming the second Phase 3 clinical trial achieves the required level of statistical significance in its primary endpoint. With the benefit of a robust preclinical and clinical data package for SGX942, we now will analyze the data to design a second Phase 3 study and will look to identify a potential partner(s) to continue this development program.

In January 2022, dusquetide proved effective at reducing tumor size in nonclinical xenograft models. Recent studies, recapitulating results from previously published studies, have confirmed the efficacy of dusquetide as a stand-alone and combination anti-tumor therapy, with radiation, chemotherapy and targeted therapy, in the context of the MCF-7 breast cancer cell line. Of note, these results are consistent with a potential direct anti-tumor effect identified with SGX942 and is another important consideration in the oral mucositis treatment space.

In June 2022, an article was published describing the binding of our Innate Defense Regulator ("IDR"), dusquetide, to the p62 protein. Dusquetide binds to p62 or SQSTM-1, a scaffold protein implicated in a number of intracellular signaling networks implicated in tumor cell survival, including autophagy. This recent publication elaborates on the direct interaction of dusquetide with p62, as well as some of the direct downstream consequences of that interaction, consistent with its observed anti-infective, anti-tumor and anti-inflammatory activities. This information advances the understanding of dusquetide's novel mechanism of action and supports the development of analogs related to dusquetide.

Oral Mucositis

Mucositis is the clinical term for damage done to the mucosa by anticancer therapies. It can occur in any mucosal region, but is most commonly associated with the mouth, followed by the small intestine. We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of mucositis, that mucositis affects approximately 500,000 people in the U.S. per year and occurs in 40% of patients receiving chemotherapy. Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral nutrition and narcotic analgesia. The GI damage causes severe diarrhea. These symptoms can limit the doses and duration of cancer treatment, leading to sub-optimal treatment outcomes.

The mechanisms of mucositis have been extensively studied and have been linked to the interaction of chemotherapy and/or radiation therapy with the innate defense system. Bacterial infection of the ulcerative lesions is regarded as a secondary consequence of dysregulated local inflammation triggered by therapy-induced cell death, rather than as the primary cause of the lesions.

We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of oral mucositis, that oral mucositis is a subpopulation of approximately 90,000 patients in the U.S., with a comparable number in Europe. Oral mucositis almost always occurs in patients with head and neck cancer treated with radiation therapy (greater than 80% incidence of severe mucositis) and is common in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

Oral BDP

BDP (beclomethasone 17,21-dipropionate) has been marketed in the U.S. and worldwide since the early 1970s as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. BDP is specifically formulated for oral administration as a single product consisting of two tablets. One tablet is intended to release BDP in the upper sections of the GI tract and the other tablet is intended to release BDP in the lower sections of the GI tract. Based on its pharmacological characteristics, BDP may have utility in treating other conditions of the GI tract having an inflammatory component, such as pediatric Crohn's disease.

SGX203 – for Treating Pediatric Crohn's Disease

SGX203 (BDP) represents a first-of-its-kind oral, locally acting therapy tailored to treat GI inflammation. Based on its pharmacological characteristics, BDP may have utility in treating multiple conditions of the GI tract having an inflammatory component. BDP has been marketed in the U.S. and worldwide since the early 1970s as the API in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. SGX203 for the treatment of pediatric Crohn's disease is specifically formulated as a two tablet delivery system for oral use that allows for administration of immediate and delayed release BDP throughout the small bowel and the colon. The FDA has given SGX203 Orphan Drug designation as well as Fast Track designation for the treatment of pediatric Crohn's disease. We will pursue a pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease contingent upon additional funding, such as through partnership funding support.

We estimate the potential worldwide market for BDP is in excess of $500 million for all applications, including the treatment of pediatric Crohn's disease. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

Pediatric Crohn's Disease

Crohn's disease causes inflammation of the GI tract. Crohn's disease can affect any area of the GI tract, from the mouth to the anus, but it most commonly affects the lower part of the small intestine, called the ileum. The swelling caused by the disease extends deep into the lining of the affected organ. The swelling can induce pain and can make the intestines empty frequently, resulting in diarrhea. Because the symptoms of Crohn's disease are similar to other intestinal disorders, such as irritable bowel syndrome and ulcerative colitis, it can be difficult to diagnose. People of Ashkenazi Jewish heritage have an increased risk of developing Crohn's disease.

Crohn's disease can appear at any age, but it is most often diagnosed in adults in their 20s and 30s. However, approximately 30% of people with Crohn's disease develop symptoms before 20 years of age. We estimate, based upon our review of historic published studies and reports, and an interpolation of data on the incidence of pediatric Crohn's disease, that pediatric Crohn's disease is a subpopulation of approximately 80,000 patients in the U.S. with a comparable number in Europe. Crohn's disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (approximately 40%) of pediatric Crohn's patients have involvement of their upper GI tract.

Crohn's disease presents special challenges for children and teens. In addition to bothersome and often painful symptoms, the disease can stunt growth, delay puberty, and weaken bones. Crohn's disease symptoms may sometimes prevent a

child from participating in enjoyable activities. The emotional and psychological issues of living with a chronic disease can be especially difficult for young people.

Public Health Solutions Overview

ThermoVax® – Thermostability Platform Technology

ThermoVax® is a novel method for thermostabilizing vaccines with a variety of adjuvants, resulting in a single vial which can be reconstituted with water for injection immediately prior to use. One of the adjuvants utilized in ThermoVax® is aluminum salts (known colloquially as "Alum"). Alum is the most widely employed adjuvant technology in the vaccine industry.

The value of ThermoVax® lies in its potential ability to eliminate the need for cold chain production, transportation, and storage for Alum-adjuvanted vaccines. This would relieve the high costs of producing and maintaining vaccines under refrigerated conditions. Based on historical reports from WHO and other scientific reports, we believe that a meaningful proportion of vaccine doses globally are wasted due to excursions from required cold chain temperature ranges. This is due to the fact that many vaccines need to be maintained either between 2 and 8 degrees Celsius ("C"), frozen below -20 degrees C, or frozen below -60 degrees C, and even brief excursions from these temperature ranges usually necessitate the destruction of the product or the initiation of costly stability programs specific for the vaccine lots in question. ThermoVax® has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines for ricin exposure in emergency settings.

ThermoVax® development, specifically in the context of an Alum adjuvant, was supported pursuant to our $9.4 million NIAID grant enabling development of thermo-stable ricin (RiVax®) and anthrax vaccines. Proof-of-concept preclinical studies with ThermoVax® indicate that it is able to produce stable vaccine formulations using adjuvants, protein immunogens, and other components that ordinarily would not withstand long temperature variations exceeding customary refrigerated storage conditions. These studies were conducted with our Alum-adjuvanted ricin toxin vaccine, RiVax® and our Alum-adjuvanted anthrax vaccine. Each vaccine was manufactured under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the key antigen. When RiVax® was kept at 40 degrees C (104 degrees Fahrenheit ("F")) for up to one year, all of the animals vaccinated with the lyophilized RiVax® vaccine developed potent and high titer neutralizing antibodies. In contrast, animals that were vaccinated with the liquid RiVax® vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C. When the anthrax vaccine was kept for up to 16 weeks at 70 degrees C, it was able to develop a potent antibody response, unlike the liquid formulation kept at the same temperature. Moreover, we also have demonstrated the compatibility of our thermostabilization technology with other secondary adjuvants such as TLR-4 agonists.

We also entered into a collaboration agreement with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine ("JABSOM"), University of Hawai'i at Manoa ("UH Manoa") and Hawaii Biotech, Inc. ("HBI") to develop a heat stable subunit Ebola vaccine. Dr. Lehrer, a co-inventor of the Ebola vaccine with HBI, has shown proof of concept efficacy with subunit Ebola vaccines in non-human primates ("NHP"). The most advanced Ebola vaccines involve the use of vesicular stomatitis virus and adenovirus vectors – live, viral vectors which complicate the manufacturing, stability and storage requirements. Dr. Lehrer's vaccine candidate is based on highly purified recombinant protein antigens, circumventing many of these manufacturing difficulties. Dr. Lehrer and HBI have developed a robust manufacturing process for the required proteins. Application of ThermoVax® may allow for a product that can avoid the need for cold chain distribution and storage, yielding a vaccine ideal for use in both the developed and developing world. This agreement has expired in accordance with its terms.

In December 2010, we executed a worldwide exclusive license agreement with the University of Colorado ("UC") for certain patents relating to ThermoVax® in all fields of use. In April 2018, the UC delivered a notice of termination of our license agreement based upon our failure to achieve one of the development milestones: initiation of the Phase 1 clinical trial of the heat stabilization technology by March 31, 2018. After negotiating with the UC, we and the UC agreed to extend the termination date to October 31, 2018 in order to allow us time to agree upon a potential agreement that would allow us to keep the rights to, and to continue to develop, the heat stabilization technology or a product candidate containing the heat stabilization technology in our field of use.

During September 2017, we were awarded funding of approximately $700,000 over five years under a NIAID Research Project (R01) grant awarded to UH Manoa for the development of a trivalent thermostabilized filovirus vaccine (including

protection against *Zaire ebolavirus*, *Sudan ebolavirus* and *Marburg Marburgvirus)*. Previous collaborations demonstrated the feasibility of developing a heat stable subunit Ebola vaccine. Under the terms of the subaward, we will continue to support vaccine formulation development with our proprietary vaccine thermostabilization technology, ThermoVax®. Ultimately, the objective is to produce a thermostable trivalent filovirus vaccine for protection against Ebola and related diseases, allowing worldwide distribution without the need for cold storage. Based on current U.S. government needs, efforts have recently been expanded to focus on a monovalent or bivalent vaccine to specifically address *Marburg marburgvirus*.

In October 2018, in a series of related transactions, (a) we and the UC agreed to terminate the original license agreement, (b) the UC and VitriVax, Inc. ("VitriVax") executed a worldwide exclusive license agreement for the heat stabilization technology for all fields of use, and (c) we and VitriVax executed a worldwide exclusive sublicense agreement, which was amended and restated in October 2020, for the heat stabilization technology for use in the fields of ricin and Ebola vaccines. We paid a $100,000 sublicense fee on the effective date of the sublicense agreement. Under the amended sublicense agreement to maintain the sublicense we are obliged to pay a minimum annual royalty of $20,000 until first commercial sale of a sublicensed product, upon which point, we shall pay an earned royalty of 2% of net sales subject to a minimum royalty of $50,000 each year. We are also required to pay royalty on any sub-sublicense income based on a declining percentage of all sub-sublicense income calculated within the contractual period until reaching a minimum of 15% after two years. In addition, we are required to pay VitriVax milestone fees of: (a) $25,000 upon initiation of a Phase 2 clinical trial of the sublicensed product, (b) $100,000 upon initiation of a Phase 3 clinical trial of the sublicensed product, (c) $100,000 upon regulatory approval of a sublicensed product, and (d) $1 million upon achieving $10 million in aggregate net sales of a sublicensed product in the U.S. or equivalent. To date none of these milestones have been met.

In March 2020, we entered into a research collaboration with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UH Manoa to further expand the filovirus collaboration to investigation of potential coronavirus vaccines, including for SARS-CoV-2 (causing COVID-19). This research collaboration will utilize the technology platform developed in the search for filovirus vaccines and will use well-defined surface glycoprotein(s) from one or more coronaviruses, which are expected to be protective for COVID-19.

During April 2020, we obtained an exclusive worldwide license for CoVaccine HT™, a novel vaccine adjuvant, from SERB Pharmaceuticals (formerly BTG Specialty Pharmaceuticals, a division of Boston Scientific Corporation) ("SERB"), for the fields of coronavirus infection (including SARS-CoV-2, the cause of COVID-19), and pandemic flu. CoVaccine HT™ is a novel adjuvant, which has been shown to enhance both cell-mediated and antibody-mediated immunity. We and our collaborators, including UH Manoa and Dr. Axel Lehrer, have successfully demonstrated the utility of CoVaccine HT™ in the development of our heat stable filovirus vaccine program, with vaccine candidates against Ebola and Marburg virus disease. Given this previous success, CoVaccine HT™ will potentially be an important component of our vaccine technology platform currently being assessed for use against coronaviruses including SARS-CoV-2, the cause of COVID-19. The license agreement was executed between us and SERB, which owns the CoVaccine HT™ intellectual property.

In September 2020, the Journal of Pharmaceutical Sciences published a scientific article detailing the thermostabilization of the filovirus GP proteins and key assays describing their stability.

During October 2020, Frontiers in Immunology published a scientific article describing CiVax™, a prototype COVID-19 vaccine, using the novel CoVaccine HT™ adjuvant and demonstrating significant immunogenicity, including strong total and neutralizing antibody responses, with a balanced Th1 response, as well as enhancement of cell mediated immunity. These are all considered to be critical attributes of a potential COVID-19 vaccine.

In December 2020, NIAID awarded us a Direct to Phase II Small Business Innovation Research ("SBIR") grant of approximately $1.5 million to support manufacture, formulation (including thermostabilization) and characterization of COVID-19 and Ebola Virus Disease ("EVD") vaccine candidates in conjunction with the CoVaccine HT™ adjuvant. This award also is supporting immune characterization of this novel, emulsified adjuvant that has unique potency and compatibility with lyophilization strategies to enable thermostabilization of subunit vaccines.

During August 2021, positive data demonstrated the efficacy of multiple filovirus vaccine candidates in NHP, including thermostabilized multivalent vaccines in a single vial platform presentation. Collaborators at UH Manoa describe the potent efficacy of vaccine candidates protecting against three life-threatening filoviruses, *Zaire ebolavirus*, *Sudan ebolavirus* and *Marburg Marburgvirus* in an article titled "Recombinant Protein Filovirus Vaccines Protect Cynomolgus Macaques from Ebola, Sudan, and Marburg Viruses", published *in Frontiers in Immunology*. These vaccine candidates contain highly purified protein antigens combined with the novel CoVaccine HT™ adjuvant, in both monovalent (single antigen) and

bivalent (two antigen) formulations. Most recently, efforts to formulate all three antigens and adjuvant into a thermostable single-vial vaccine platform has also been shown to protect 75% of vaccinated NHPs against subsequent *Sudan ebolavirus* challenge, with further development to test efficacy against other filovirus infections ongoing.

During August 2021, *Vaccine* published a scientific article describing the formulation of single-vial platform presentations of monovalent (single antigen), bivalent (two antigens) and trivalent (three antigens) combinations of filovirus vaccine candidates.

During September 2021, an accelerated preprint was posted on bioRxiv of pre-clinical immunogenicity studies for CiVax™ (heat stable COVID-19 vaccine program) demonstrating durable broad-spectrum neutralizing antibody responses, including against the Beta, Gamma and Delta variants of concern. The scientific article is part of the ongoing collaboration with Axel Lehrer, PhD, Associate Professor at the Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UH Manoa. Development continues under a non-dilutive $1.5M grant from the NIAID awarded to us in December 2020.

In December 2021, 100% protection of NHPs against lethal Sudan ebolavirus challenge was achieved using a bivalent, thermostabilized vaccine formulated in a single vial, reconstituted only with water immediately prior to use. This milestone is part of an ongoing collaboration with UH Manoa and further demonstrates the broad applicability of the vaccine platform, and its potential role in the U.S. government's initiative for pandemic preparedness.

In May 2022, the United States Patent and Trademark Office issued a Notice of Allowance for the patent application titled “Composition and Methods of Manufacturing Trivalent Filovirus Vaccines.” The allowed claims are directed to unique, proprietary composition and methods directed to combinations of glycoprotein antigens with nano-emulsion adjuvants comprising sucrose fatty acid esters prior to lyophilization. The described vaccine platform has previously been successfully applied to filovirus vaccines (as mono-, bi- and tri-valent candidates for *Zaire ebolavirus, Sudan ebolavirus* and *Marburg marburgvirus*) as well as SARS-CoV-2 vaccine.

In June 2022, 100% protection of NHPs against lethal *Marburg marburgvirus* challenge was achieved using a bivalent, thermostabilized vaccine formulated in a single vial, reconstituted only with sterile water immediately prior to use. This important milestone is part of an ongoing collaboration with UH Manoa, demonstrating the successful presentation of one or more antigen(s) within the same formulation while maintaining full potency and thermostability. It further demonstrates the broad applicability of the heat stable vaccine platform, and its potential role in the U.S. government's initiative for pandemic preparedness.

RiVax® – Ricin Toxin Vaccine

RiVax® is our proprietary vaccine candidate being developed to protect against exposure to ricin toxin and if approved, would be the first ricin vaccine. The immunogen in RiVax® induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated ricin A chain subunit that is enzymatically inactive and lacks residual toxicity of the holotoxin. RiVax® has demonstrated statistically significant ($p < 0.0001$) preclinical survival results, providing 100% protection against acute lethality in an aerosol exposure non-human primate model (Roy et al, 2015, Thermostable ricin vaccine protects rhesus macaques against aerosolized ricin: Epitope-specific neutralizing antibodies correlate with protection, PNAS USA 112:3782-3787), and has also been shown to be well tolerated and immunogenic in two Phase 1 clinical trials in healthy volunteers. Results of the first Phase 1 human trial of RiVax® established that the immunogen was safe and induced antibodies that we believe may protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The outcome of this study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, A Pilot Clinical Trial of a Recombinant Ricin Vaccine in Normal Humans, PNAS, 103:2268-2273). The second trial that was completed in September 2012 and was sponsored by University of Texas Southwestern Medical Center (“UTSW”) evaluated a more potent formulation of RiVax® that contained an Alum adjuvant. The results of the Phase 1b study indicated that Alum-adjuvanted RiVax® was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax®. The outcomes of this second study were published in the Clinical and Vaccine Immunology.

We have adapted the original manufacturing process for the immunogen contained in RiVax® for thermostability and large scale manufacturing and recent studies have confirmed that the thermostabilized RiVax® formulation enhances the stability of the RiVax® antigen, enabling storage for at least 1 year at temperatures up to 40 degrees C (104 degrees F). The program

will pursue approval via the FDA "Animal Rule" since it is not possible to test the efficacy of the vaccine in a clinical study which would expose humans to ricin. Uniform, easily measured and species-neutral immune correlates of protection that can be measured in humans and animals, and are indicative of animal survival to subsequent ricin challenge, are central to the application of the "Animal Rule." Recent work has identified such potential correlates of immune protection in animals and work to qualify and validate these approaches is continuing, with the goal of utilizing these assays in a planned Phase 1/2 clinical trial with the thermostable RiVax® formulation. During September 2018, we published an extended stability study of RiVax®, showing up to 100% protection in mice after 12 months storage at 40 degrees C (104 degrees F) as well as identification of a potential in vitro stability indicating assay, critical to adequately confirming the long-term shelf life of the vaccine. We have entered into a collaboration with IDT Biologika GmbH ("IDT") to scale-up the formulation/filling process and continue development and validation of analytical methods established at IDT to advance the program. We also initiated a development agreement with Emergent BioSolutions, Inc. ("EBS") to implement a commercially viable, scalable production technology for the RiVax® drug substance protein antigen.

The development of RiVax® has been sponsored through a series of overlapping challenge grants, UC1, and cooperative grants, U01, from the NIH, granted to us and to UTSW where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. To date, we and UTSW have collectively received approximately $25 million in grant funding from the NIH for the development of RiVax®. In September 2014, we entered into a contract with the NIH for the development of RiVax® pursuant to which we were awarded an additional $21.2 million of funding in the aggregate. The development agreements with EBS and IDT were specifically funded under this NIH contract.

In 2017, NIAID exercised options to fund additional animal efficacy studies and good manufacturing practices compliant RiVax® bulk drug substance and finished drug product manufacturing, which is required for the conduct of future preclinical and clinical safety and efficacy studies. The exercised options provide us with approximately $4.5 million in additional non-dilutive funding, bringing the total amount awarded to date under this contract to $21.2 million, which expired in February 2021. The total award of up to $21.2 million supported the preclinical, manufacturing and clinical development activities necessary to advance heat stable RiVax® with the FDA. In addition to this funding for the development of RiVax®, biomarkers for RiVax® testing have been successfully identified, facilitating potential approval under the FDA Animal Rule.

During December 2019, we initiated a third Phase 1 double-blind, placebo-controlled, randomized study in eight healthy adult volunteer subjects designed to evaluate the safety and immunogenicity of RiVax® utilizing ThermoVax®. During January 2020, we suspended the study after Emergent Manufacturing Operations Baltimore LLC ("EMOB"), the manufacturer of the drug substance, notified us that, after releasing the final drug product to us, EMOB identified that the active drug substance tested outside the established specification parameters. Two subjects had received doses as part of the study before the manufacturer provided this notice. Those two subjects were monitored with no safety issues noted and data was captured in accordance with the study protocol. They did not receive further doses of study drug.

During April 2020, we received notification from NIAID that they would not be exercising the final contract option to support the conduct of a Phase 1/2 clinical study in healthy volunteers. As a result, the total contract award will not exceed $21.2 million. This contract expired in February 2021.

In connection with failures relating to the manufacture of RiVax® bulk drug substance, on July 1, 2020, we filed a demand for arbitration against EBS, Emergent Product Development Gaithersburg, Inc. ("EPDG"); and EMOB (together with EBS and EPDG, "Emergent") with the American Arbitration Association in Mercer County, New Jersey. We have alleged that (a) EPDG breached contracts, (b) EMOB breached contracts; and (c) Emergent fraudulently induced us into entering into the contracts with EPDG and EMOB. We sought to recover damages in excess of $19 million from Emergent. Emergent answered the demand for arbitration denying the allegations and asserting affirmative defenses. We presented our case at an arbitration hearing over 12 days in January 2022. Following submission of post-hearing briefs, the arbitration panel heard closing oral arguments in April 2022. On July 6, 2022, the American Arbitration Association entered a final decision in connection with this arbitration. Despite the arbitration panel ruling that Emergent had committed a number of breaches of the parties' contracts, the panel did not award monetary damages. On September 30, 2022, we filed a petition to vacate the arbitration decision with the Delaware Court of Chancery, requesting that the Court vacate the arbitration decision and remand the matter to the arbitration panel for rehearing. We cannot offer any assurances as to any result of our challenge of the arbitration decision or that we will recover any damages from Emergent. For more details regarding the arbitration against Emergent, see Part I – Item 3. "Legal Proceedings" in this Annual Report.

In November 2021, an article was published on pre-clinical immunogenicity studies for RiVax® demonstrating enduring protection for at least 12 months post-vaccination. These results, coupled with the previous demonstration of efficacy in

mice and NHPs as well as long-term thermostability (at least 1 year at 40 degrees C or 104 degrees F), reinforce the practicality of stockpiling and potentially utilizing the RiVax® vaccine in warfighters and civilian first responders without the complexities that arise for vaccines that require stringent cold chain handling.

RiVax® has been granted Orphan Drug designation as well as Fast Track designation by the FDA for the prevention of ricin intoxication. In addition, RiVax® has also been granted Orphan Drug designation in the European Union ("EU") from the EMA Committee for Orphan Medical Products.

Assuming development efforts are successful for RiVax®, we believe potential government procurement contract(s) could reach as much as $200 million. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

As a new chemical entity, an FDA approved RiVax® vaccine has the potential to qualify for a biodefense Priority Review Voucher ("PRV"). Approved under the 21st Century Cures Act in late 2016, the biodefense PRV is awarded upon approval as a medical countermeasure when the active ingredient(s) have not been otherwise approved for use in any context. PRVs are transferable and can be sold, with sales in recent years of approximately $100 million. When redeemed, PRVs entitle the user to an accelerated review period of nine months, saving a median of seven months review time as calculated in 2009. However, FDA must be advised 90 days in advance of the use of the PRV and the use of a PRV is associated with an additional user fee ($1.3 million for fiscal year 2022).

In July 2022, we signed a worldwide exclusive agreement to license and supply our ricin antigen, used in our RiVax® vaccine, to SERB, for development of a novel therapeutic treatment against ricin toxin poisoning. In pursuit of a ricin antidote, SERB will leverage its unique broad-spectrum polyclonal antibody platform, gained in its acquisition of BTG Specialty Pharmaceuticals. This specialized manufacturing process generates binding fragments from antibodies that are specific to a given antigen, helping to ensure potency and purity. This platform is currently used to manufacture two of SERB's currently marketed products, CroFab® and DigiFab®.

Ricin Toxin

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigation Bioterror report released in November 2007 titled Terrorism 2002-2005, which states that "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations." Al Qaeda in the Arabian Peninsula had threatened the use of ricin toxin to poison food and water supplies and in connection with explosive devices. Domestically, the threat from ricin remains a concern for security agencies. In April 2013, letters addressed to the U.S. President, a Senator and a judge tested positive for ricin. As recently as September 2020, ricin-laced letters addressed to the White House and others addressed to Texas law enforcement agencies were intercepted before delivery raising fresh concerns about the deadly toxin.

The Centers for Disease Control and Prevention has classified ricin toxin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. The recent ricin threat to government officials has heightened the awareness of this toxic threat. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield nor is there a known antidote for ricin toxin exposure.

SGX943 – for Treating Emerging and/or Antibiotic-Resistant Infectious Diseases

SGX943 is an IDR, containing the same active ingredient as SGX942. Dusquetide is a fully synthetic, 5-amino acid peptide with high aqueous solubility and stability. Extensive *in vivo* preclinical studies have demonstrated enhanced clearance of bacterial infection with SGX943 administration. SGX943 has shown efficacy against both Gram-negative and Gram-positive bacterial infections in preclinical models, independent of whether the bacteria is antibiotic-resistant or antibiotic-sensitive.

The innate immune system is responsible for rapid and non-specific responses to combat bacterial infection. Augmenting these responses represents an alternative approach to treating bacterial infections. In animal models, IDRs are efficacious against both antibiotic-sensitive and antibiotic-resistant infections, both Gram-positive and Gram-negative bacteria, and are active irrespective of whether the bacteria occupy a primarily extracellular or intracellular niche. IDRs are also effective as stand-alone agents or in conjunction with antibiotics. An IDR for the treatment of serious bacterial infections encompasses a number of clinical advantages including:

- Treatment when antibiotics are contraindicated, such as:
    - before the infectious organism and/or its antibiotic susceptibility is known; or
    - in at-risk populations prior to infection.
- An ability to be used as an additive, complementary treatment with antibiotics, thereby:
    - enhancing efficacy of sub-optimal antibiotic regimens (e.g., partially antibiotic-resistant infections);
    - enhancing clearance of infection, thereby minimizing the generation of antibiotic resistance (e.g., in treating melioidosis); and
    - reducing the required antibiotic dose, again potentially minimizing the generation of antibiotic resistance.
- An ability to modulate the deleterious consequences of inflammation in response to the infection, including the inflammation caused by antibiotic-driven bacterial lysis.
- Being unlikely to generate bacterial resistance since the IDR acts on the host, and not the pathogen.

Importantly, systemic inflammation and multi-organ failure is the ultimate common outcome of not only emerging and/or antibiotic-resistant infectious diseases, but also of most biothreat agents (e.g., *Burkholderia pseudomallei*), indicating that dusquetide would be applicable not only to antibiotic-resistant infection, but also to biothreat agents, especially where the pathogen is not known and/or has been engineered for enhanced antibiotic resistance.

In May 2019, we were awarded a DTRA subcontract of approximately $600,000 over three years to participate in a biodefense contract for the development of medical countermeasures against bacterial threat agents. As of December 31, 2022, there was negligible revenue earned or expense incurred related to the DTRA subcontract.

The Drug Approval Process

The FDA and comparable regulatory agencies in state, local and foreign jurisdictions impose substantial requirements on the clinical development, manufacture and marketing of new drug and biologic products. The FDA, through regulations that implement the Federal Food, Drug, and Cosmetic Act, as amended (“FDCA”), and other laws and comparable regulations for other agencies, regulate research and development activities and the testing, manufacture, labeling, storage, shipping, approval, recordkeeping, advertising, promotion, sale, export, import and distribution of such products. The regulatory approval process is generally lengthy, expensive and uncertain. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products, including holds on clinical research, civil or criminal fines or other penalties, product recalls, or seizures, or total or partial suspension of production or injunctions, refusals to permit products to be imported into or exported out of the U.S., refusals of the FDA to grant approval of drugs or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications and criminal prosecutions.

Before human clinical testing in the U.S. of a new drug compound or biological product can commence, an Investigational New Drug (“IND”), application is required to be submitted to the FDA. The IND application includes results of pre-clinical animal studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

Clinical trials are normally done in three phases, although the phases may overlap. Phase 1 trials are smaller trials concerned primarily with metabolism and pharmacologic actions of the drug and with the safety of the product. Phase 2 trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase 3 trials are expanded clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase 4, or post-marketing, studies to be conducted.

With certain exceptions, once successful clinical testing is completed, the sponsor can submit a NDA, for approval of a drug, or a Biologic License Application ("BLA"), for biologics such as vaccines, which will be reviewed, and if successful, approved by the FDA, allowing the product to be marketed. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. Furthermore, the FDA or any foreign health authority may not grant an approval on a timely basis, if at all. The FDA may deny the approval of a NDA or BLA, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing practice regulations. In complying with standards contained in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by, or under the authority of, the FDA and by other federal, state, local or foreign agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase 4 post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the marketing of a product as a treatment for clinical indications other than those for which the product was initially tested. For certain drugs intended to treat serious, life-threatening conditions that show great promise in earlier testing, the FDA can also grant conditional approval. However, drug developers are required to study the drug further and verify clinical benefit as part of the conditional approval provision, and the FDA can revoke approval if later testing does not reproduce previous findings. The FDA may also condition approval of a product on the sponsor agreeing to certain mitigation strategies that can limit the unfettered marketing of a drug. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the product. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes will likely be required to be submitted to the FDA or foreign regulatory authority.

In the U.S., the FDCA, the Public Health Service Act, the Federal Trade Commission Act, and other federal and state statutes and regulations govern, or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drug, biological, medical device and food products. Noncompliance with applicable requirements can result in, among other things, fines, recall or seizure of products, refusal to permit products to be imported into the U.S., refusal of the government to approve product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution. The FDA may also assess civil penalties for violations of the FDCA involving medical devices.

For biodefense development, such as with RiVax®, the FDA has instituted policies that are expected to result in shorter pathways to market. This potentially includes approval for commercial use utilizing the results of animal efficacy trials, rather than efficacy trials in humans. However, we will still have to establish that the vaccine and countermeasures it is developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the benefit-risk scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the animal rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the animal rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require

safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations.

Vaccines are approved under the BLA process that exists under the Public Health Service Act. In addition to the greater technical challenges associated with developing biologics, the potential for generic competition is lower for a BLA product than a small molecule product subject to a NDA under the Federal Food, Drug and Cosmetic Act. Under the Patient Protection and Affordable Care Act enacted in 2010, a "generic" version of a biologic is known as a biosimilar and the barriers to entry – whether legal, scientific, or logistical – for a biosimilar version of a biologic approved under a BLA are higher.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition – generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting a NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs or biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug or biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track drug or biologic concurrent with, or after, the filing of the IND for the candidate. The FDA must determine if the drug or biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. Unique to a fast track product, the FDA may initiate review of sections of a fast track product's NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA or BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means the FDA may approve the product based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug or biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Paediatric Investigation Plan

As part of the regulatory process for the registration of new medicines with the EMA and the MHRA, pharmaceutical companies are required to provide a PIP outlining the Company's strategy for investigation of the new medicinal products in the paediatric population. In some instances, a waiver negating the need for a PIP for certain conditions may be granted by the EMA or MHRA when development of a medicine for use in children is not feasible or appropriate.

Innovative Licensing and Access Pathway

The ILAP was launched in the UK at the start of 2021 to accelerate the development and access to promising medicines, thereby facilitating patient access to new medicines. The pathway, part of the UK's plan to attract life sciences development in the post-Brexit era, features enhanced input and interactions with the MHRA and other stakeholders including the NICE, and the SMC. The decision to award the Innovation Passport is made by an ILAP Steering Group, which is comprised of representatives from MHRA, NICE, and SMC. The Innovation Passport designation is the first step in the ILAP process and triggers the MHRA and its partner agencies to create a target development profile to chart out a roadmap for regulatory and development milestones with the goal of early patient access in the UK. Other benefits of ILAP include a 150-day accelerated assessment, rolling review and a continuous benefit risk assessment.

Early Access to Medicines Scheme

Launched in April 2014 in the United Kingdom by the MHRA, the Early Access to Medicines Scheme ("EAMS") offers severely ill patients with life-threatening and seriously debilitating conditions the lifeline of trying ground-breaking new medicines earlier than they would normally be accessible. PIM designation is the first phase of EAMS and is awarded following an assessment of early nonclinical and clinical data by the MHRA. The criteria product candidates must meet to obtain PIM designation are:

- Criterion 1 – The condition should be life-threatening or seriously debilitating with a high unmet medical need (i.e., there is no method of treatment, diagnosis or prevention available or existing methods have serious limitations).

- Criterion 2 – The medicinal product is likely to offer major advantage over methods currently used in the UK.

- Criterion 3 – The potential adverse effects of the medicinal product are likely to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit risk balance. A positive benefit risk balance should be based on preliminary scientific evidence that the safety profile of the medicinal product is likely to be manageable and acceptable in relation to the estimated benefits.

False Claims Laws

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government.

Anti-Kickback Laws

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in

return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other.

United States Healthcare Reform

Federal Physician Payments Sunshine Act and its implementing regulations require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates" – independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Third-Party Suppliers and Manufacturers

Drug substance and drug product manufacturing is outsourced to qualified suppliers. We do not have manufacturing capabilities/infrastructure and do not intend to develop the capacity to manufacture drug products substances. We have agreements with third-party manufacturers to supply bulk drug substances for our product candidates and with third parties to formulate, package and distribute our product candidates. Our employees include professionals with expertise in pharmaceutical manufacturing development, quality assurance and third-party supplier management who oversee work conducted by third-party companies. We believe that we have on hand or can easily obtain sufficient amounts of product candidates to complete our currently contemplated clinical trials. All of the drug substances used in our product candidates currently are manufactured by single suppliers. While we have not experienced any supply disruptions, the number of manufacturers of the drug substances is limited. In the event it is necessary or advisable to acquire supplies from alternative suppliers, assuming commercially reasonable terms could be reached, the challenge would be the efficient transfer of technology and know-how from current manufactures to the new supplier. Formulation and distribution of our finished product candidates also currently are conducted by single suppliers but we believe that alternative sources for these services are readily available on commercially reasonable terms, subject to the efficient transfer of technology and know-how from current suppliers to the new supplier.

All of the current agreements for the supply of bulk drug substances for our product candidates and for the formulation or distribution of our product candidates relate solely to the development (including preclinical and clinical) of our product candidates. Under these contracts, our product candidates are manufactured upon our order of a specific quantity. In the event that we obtain marketing approval for a product candidate, we will qualify secondary suppliers for all key manufacturing activities supporting the marketing application.

Marketing and Collaboration

We do not currently have any sales and marketing capability, other than to potentially market our biodefense vaccine products directly to government agencies. With respect to other commercialization efforts, we currently intend to seek distribution and other collaboration arrangements for the sales and marketing of any product candidate that is approved, while also evaluating the potential to commercialize on our own in orphan disease indications. From time to time, we have had and are having strategic discussions with potential collaboration partners for our biodefense vaccine product

candidates, although no assurance can be given that we will be able to enter into one or more collaboration agreements for our product candidate on acceptable terms, if at all. We believe that both military and civilian health authorities of the U.S. and other countries will increase their stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions that could ensue following a bioterrorism attack.

On December 20, 2012, we re-acquired the North American and European commercial rights to BDP through an amendment of our collaboration and supply agreement with Sigma-Tau Pharmaceuticals, Inc., which is now known as Leadiant Biosciences, Inc. ("Leadiant"). The amendment requires us to make certain approval and commercialization milestone payments to Leadiant which could reach up to $6 million. In addition, we have agreed to pay Leadiant: (a) a royalty amount equal to 3% of all net sales of BDP made directly by us, and any third-party partner and/or their respective affiliates in the U.S., Canada, Mexico and in each country in the European Territory for the later to occur of: (i) a period of ten years from the first commercial sale of BDP in each country, or (ii) the expiration of our patents and patent applications relating to BDP in such country (the "Payment Period"); and (b) 15% of all up-front payments, milestone payments and any other consideration (exclusive of equity payments) received by us and/or a potential partner from us and/or potential partner's licensees, distributors and agents for BDP in each relevant country in the territory, which amount will be paid on a product-by-product and a country-by-country basis for the Payment Period.

On August 25, 2013, we entered into an agreement with SciClone, pursuant to which SciClone provided us with access to its oral mucositis clinical and regulatory data library in exchange for exclusive commercialization rights for SGX942 in the People's Republic of China, including Hong Kong and Macau, subject to the negotiation of economic terms. SciClone's data library was generated from two sequential Phase 2 clinical studies conducted in 2010 and 2012 evaluating SciClone's compound, SCV-07, for the treatment of oral mucositis caused by chemoradiation therapy in head and neck cancer patients, before SciClone terminated its program. By analyzing data available from the placebo subjects in the SciClone trials, we acquired valuable insight into disease progression, along with quantitative understanding of its incidence and severity in the head and neck cancer patient population. This information assisted us with the design of the SGX942 Phase 2 clinical trial, in which positive preliminary results were announced in December 2015.

On September 9, 2016, we and SciClone entered into an exclusive license agreement, pursuant to which we granted rights to SciClone to develop, promote, market, distribute and sell SGX942 in the People's Republic of China, including Hong Kong and Macau, as well as Taiwan, South Korea and Vietnam. Under the terms of the license agreement, SciClone will be responsible for all aspects of development, product registration and commercialization in the territories, having access to data generated by us. In exchange for exclusive rights, SciClone will pay us royalties on net sales, and we will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights. We also entered into a common stock purchase agreement with SciClone pursuant to which we sold 23,530 shares of our common stock to SciClone for approximately $127.50 per share, for an aggregate price of $3 million.

Competition

Our competitors are pharmaceutical and biotechnology companies, most of whom have considerably greater financial, technical, and marketing resources than we do. Universities and other research institutions, including the U.S. Army Medical Research Institute of Infectious Diseases, also compete in the development of treatment technologies, and we face competition from other companies to acquire rights to those technologies.

HyBryte™ Competition

The FDA has approved several treatments for later stages (IIB-IV) of CTCL and/or in conditions that are unresponsive to prior treatment. Three are targeted therapies (Targretin®-caps, Ontak® and Adcetris®), two are histone deacetylases inhibitors (Zolina® and Istodax®) and the remaining two are topical therapies (Valchor® and Targretin®-gel). There are currently no FDA approved therapies for the treatment of front-line, early stage (I-IIA) CTCL; however certain topical chemotherapies and topical, radiation, photodynamic and other therapies which are approved for indications other than CTCL are prescribed off-label for the treatment of early stage CTCL. These include narrow-band ultraviolet B (NB-UVB) light therapy and psoralen combined with ultraviolet A UVA light therapy ("PUVA"); however, PUVA treatments are usually limited to three times per week and 200 times in total due to the potentially carcinogenic side effect, while NB UVB is known to be effective against patches but less so against plaque lesions, common in early stage CTCL. There are other drugs currently in development that may have the potential to be used in early stage (I-IIA) CTCL, primarily in early Phase 1 and 2 clinical studies. Other treatments for later stage disease are not considered direct competitors.

SGX94/942 Competition

Because SGX94 (dusquetide) uses a novel mechanism of action in combating bacterial infections, there are no direct competitors at this time. Bacterial infections are routinely treated with antibiotics and SGX94 treatment is anticipated to be utilized primarily where antibiotics are insufficient (e.g., due to antibiotic resistance) or contra-indicated (e.g., in situations where the development of antibiotic resistance is a significant concern). Many groups are working on the antibiotic resistance problem and research into the innate immune system is intensifying, making emerging competition likely (from companies such as Celtaxsys Inc., Innaxon Therapeutics and Innate Pharma SA).

There is currently one drug approved for the treatment of oral mucositis in hematological cancer (palifermin). There are currently no approved drugs for treatment of oral mucositis in cancers with solid tumors (e.g., head and neck cancer). There are several drugs in clinical development for oral mucositis – two in Phase 3 (brilacidin by Innovation Pharmaceuticals, Inc., and a mucobuccal tablet by Monopar Therapeutics LLC) and one submitted for a NDA (GC4419 by Galera Therapeutics, Inc.). There are various natural products in small and/or open label studies (including sage, turmeric, honey and olive oil). In addition, there are medical devices approved for the treatment of oral mucositis including MuGard®, GelClair®, Episil®, and Caphosol®. These devices attempt to create a protective barrier around the oral ulceration with no biologic activity in treating the underlying disease.

Oral BDP Competition

There are a number of approved treatments for Crohn's disease and additional compounds are in late-stage development.

Enbrel® (etanercept), Remicade® (infliximab) and Humira® (adalimumab) are currently approved for the treatment of pediatric Crohn's disease; however, all carry significant Black Box warnings in their labeling for increased risk of serious infection and malignancy, and therefore are approved for treatment of moderate to severe patients. Entocort® (enteric-coated budesonide) is currently approved for the treatment of mild to moderate active Crohn's disease involving the lower GI tract (ileum and/or the ascending colon) in patients eight years of age and older who weigh more than 25 kilograms. There is one other marketed biologic, Tysabri® (natalizumab), in a Phase 2 study for pediatric Crohn's.

ThermoVax® Competition

Multiple groups and companies are working to address the unmet need of vaccine thermostability using a variety of technologies. In addition, other organizations, such as the Bill and Melinda Gates Foundation and PATH, have programs designed to advance technologies to address this need.

Several stabilization technologies currently being developed involve mixing vaccine antigen +/- adjuvant with various proprietary excipients or co-factors that either serve to stabilize the vaccine or biological product in a liquid or dried (lyophilized) form. Examples of these approaches include the use of various plant-derived sugars and macromolecules being developed by companies such as iosBio. Variation Biotechnologies, Inc. ("VBI") is developing a lipid system (resembling liposomes) to stabilize viral antigens, including virus-like particles ("VLPs"), and for potential application to a conventional influenza vaccine among others.

Additionally, companies like Altimmune, Inc., and Panacea Biotec Ltd., and Compass Biotech Inc. are developing proprietary vaccines with the application of some form of stabilization technology.

Public Health Solutions Competition

We face competition in the area of biodefense product development from various public and private companies, universities and governmental agencies, such as the U.S. Army, some of whom may have their own proprietary technologies which may directly compete with our technologies.

The U.S. Army Medical Research Institute of Infectious Diseases, the DoD's lead laboratory for medical research to counter biological threats is also developing a ricin vaccine candidate, RVEc™. RVEc™ has been shown to be fully protective in mice exposed to lethal doses of ricin toxin by the aerosol route. Further studies, in both rabbits and nonhuman primates, were conducted to evaluate RVEc™'s safety as well as its immunogenicity, with positive results observed. No further data

has been released in recent years. A monoclonal antibody is also being developed by Mapp Biopharmaceutical Inc. as a ricin therapeutic, with administration 4 hours after exposure demonstrating efficacy while administration 12 hours after ricin exposure was not protective in animal models.

Patents and Other Proprietary Rights

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary knowledge and experience that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements, which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

In 2014, we acquired a novel PDT that utilizes safe visible light for activation, which we refer to as HyBryte™. The active ingredient in HyBryte™ is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. As part of the acquisition, we acquired a license agreement relating to the use of photo-activated hypericin, composition of matter patent for HyBryte™ (U.S. patent 8,629,302) and additional issued and pending applications, both in the U.S. and abroad. U.S. patent 8,629,302 is expected to expire in September 2030. In August 2018, we were granted a U.S. patent (No. 10,053,513) titled “Systems and Methods for Producing Synthetic Hypericin.” This newly issued patent, expected to expire in 2036, broadens the production around synthetic hypericin. Our proprietary formulation of synthetic hypericin also has been granted a European patent for the treatment of psoriasis, EP 2571507, and complements the method of treatment claims covered by the previously issued U.S. patent 6001882, Photoactivated hypericin and the use thereof. Further, on January 7, 2020, we also were granted a U.S. patent (No. 10,526,268) titled “Systems and Methods for Producing Synthetic Hypericin”, which further expanded protection for the composition of purified synthetic hypericin. This patent is also expected to expire in 2036. Patent protection is also pursued worldwide with similar patents and expiry dates.

In addition to issued and pending patents, we also have “Orphan Drug” designations for HyBryte™ in the U.S. and the EU for CTCL, SGX203 in the U.S. for pediatric Crohn’s disease, as well as for RiVax® in the U.S. and EU. Our Orphan Drug designations provide for seven years of post-approval marketing exclusivity in the U.S. and ten years exclusivity in Europe. We have pending patent applications for this indication that, if granted, may extend our anticipated marketing exclusivity beyond the U.S. seven year or EU ten year post-approval exclusivity provided by Orphan Drug legislation.

In 2013, we expanded our patent portfolio to include innate defense regulation through the acquisition of the novel drug technology, known as SGX94. By binding to the pivotal regulatory protein p62, also known as sequestosome-1, SGX94 regulates the innate immune system to reduce inflammation, eliminate infection and enhance healing. As part of the acquisition, we acquired all rights, including composition of matter patents for SGX94 as well as other analogs and crystal structures of SGX94 with its protein target p62, including U.S. patent 8,124,721 (expiring 2028), 9,416,157 (expiring 2028) and 8,791,061 (expiring 2029), both in the U.S. and abroad. SGX94 was developed pursuant to discoveries made by Professors B. Brett Finlay and Robert Hancock of University of British Columbia (“UBC”). We also have rights to the background technology patents (U.S. patent numbers 7,507,787 [expiring 2024], 7,687,454 [expiring 2026] and 11,311,598 [expiring 2034]). The U.S. Patent Office has also granted patents titled “Novel Peptides and Analogs for Use in the Treatment of Oral Mucositis.” The issued patents (U.S. patent numbers 9,850.279 and 10,253,068, both expiring in 2034) claim therapeutic use of dusquetide and related IDR analogs, and adds to composition of matter claims for dusquetide and related analogs that have been granted in the U.S. and worldwide.

We have issued U.S. patent 8,263,582 that covers the use of BDP for treating inflammatory disorders of the gastrointestinal tract, which patent expired on March 15, 2022. We also have European patent EP 1392321 claiming the use of topically active corticosteroids in orally administered dosage forms that act concurrently to treat inflammation in the upper and lower gastrointestinal tract, as well as European patent EP 2242477 claiming the use of orally ingested BDP for treatment of

interstitial lung disease. European patents EP 1392321 and EP 2242477 expired in March 2022 and expire on January 2029, respectively.

The subject of U.S. patent application number 12/633,631 filed December 8, 2009 and continued into patent application 15/495,798 filed April 24, 2017 and corresponding European patent application number 09836727.9, which was granted a patent 2373160 in October 2017 and pursued in multiple European countries, is the use of topically active BDP in radiation and chemotherapeutics injury. Additionally, we have numerous patent filings currently issued or pending in foreign jurisdictions covering this subject matter, including Australia, Canada, China, Hong Kong, Israel, Japan, South Korea and New Zealand.

ThermoVax® is the subject of U.S. patents 8,444,991 (expiring February 2030) and 8,808,710 (expiring March 2028) both issued on May 21, 2013 titled "Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition" and licensed to us by VitriVax, Inc. ThermoVax® is also U.S. patent application number 15/694.023 filed September 17, 2017 titled "Thermostable Vaccine Compositions and Methods of Preparing Same" and jointly invented by the UC and the Company. The patent application and the corresponding foreign filings are pending or granted and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement covers thermostable alum-adjuvanted vaccines for ricin toxin and Ebola virus. An additional patent, covering vaccine combinations such as ricin toxin and anthrax, was filed in 2015 and granted on May 21, 2019 in the U.S. (No. 10,293,041, titled "Multivalent Stable Vaccine Composition and Methods of Making Same") and is expected to expire in 2035. A patent for unique, proprietary compositions and methods directed to combinations of glycoprotein antigens with nanoemulsion adjuvants comprising sucrose fatty acid esters prior to lyophilization was filed in 2020, granted in 2022 and expiring in 2040 (No. 11,433,129 titled "Compositions and Methods of Manufacturing Trivalent Filovirus Vaccines.") Patent protection is also pursued worldwide with similar patents and expiry dates.

Additional vaccine thermostabilization patents specific for anti-viral vaccines, including filovirus and coronavirus have been filed but are not yet granted. If granted, expiry dates would range from 2040 to 2041. Patent protection is also pursued worldwide with similar patents and expiry dates.

HyBryte™ License Agreement

In September 2014, we acquired a worldwide exclusive license agreement with New York University and Yeda Research and Development Company Ltd. for the rights to a novel PDT that utilizes safe visible light for activation, which we refer to as HyBryte™. To maintain this license, we are obligated to pay $25,000 in annual license fees. In addition, we will pay the licensors: (a) a royalty amount equal to 3% of all net sales of HyBryte™ made directly by us and/or any affiliates; (b) a royalty amount equal to 2.5% of all net sales of HyBryte™ made by our sublicensees, subject to stated maximums and (c) 20% of all payments, not based on net sales, received by us from our sublicensees. This license may be terminated by either party upon notice of a material breach by the other party that is not cured within the applicable cure period. The exclusive license includes rights to several issued U.S. patents, including U.S. patent numbers 6,867,235 and 7,122,518, among other domestic and foreign patent applications. U.S. Patent numbers 6,867,235 and 7,122,518 expired in January 2020 and is expected to expire in November 2023, respectively.

We acquired the license agreement for HyBryte™ and related intangible assets, including U.S. patent 8,629,302, properties and rights pursuant to an asset purchase agreement with Hy Biopharma Inc. ("Hy Biopharma"). As consideration for the assets acquired, we initially paid $275,000 in cash and issued 12,328 shares of common stock with a market value of $3,750,000, and in March 2020 we issued 130,413 shares of common stock at a value of $5,000,000 (based upon an effective per share price of $38.40) as a result of HyBryte™ demonstrating statistical significant treatment response in the Phase 3 clinical trial. Provided the final success-orientated milestone is attained, we will be required to make a payment of up to $5 million, if and when achieved, payable in our common stock.

SGX94 License Agreements

On December 18, 2012, we acquired a first in class drug technology, known as SGX94 (dusquetide), representing a novel approach to modulation of the innate immune system. SGX94 is an IDR that regulates the innate immune system to reduce inflammation, eliminate infection and enhance tissue healing by binding to the pivotal regulatory protein p62, also known as sequestosome-1. As part of the acquisition, we acquired all rights, including composition of matter patents, preclinical and Phase 1 clinical study datasets for SGX94. We also assumed a license agreement with UBC to advance the research and

development of the SGX94 technology. The license agreement with UBC provides us with exclusive worldwide rights to manufacture, distribute, market sell and/or license or sublicense products derived or developed from this technology. Under the license agreement we are obligated to pay UBC (i) an annual license maintenance fee of CAD $1,000, and (ii) milestone payments which could reach up to CAD $1.2 million. This license agreement (a) will automatically terminate if we file, or become subject to an involuntary filing, for bankruptcy, and (b) may be terminated by UBC in the event of, among other things, our insolvency, dissolution, grant of a security interest in the technology licensed to us pursuant to the license agreement, or material breach of or failure to perform material obligations under the license agreement or other research agreements between us and UBC.

Oral BDP License Agreement

On November 24, 1998, the Company, known at the time as Enteron Pharmaceuticals, Inc. ("Enteron") and George B. McDonald ("Dr. McDonald") entered into an exclusive license agreement for the rights to intellectual property, including know-how, relating to BDP. We have an exclusive license to commercially exploit the covered products worldwide, subject to Dr. McDonald's right to make and use the technology for research purposes and the U.S. Government's right to use the technology for government purposes. Pursuant to the license agreement, as amended, we are required to (i) reimburse Dr. McDonald for certain out-of-pocket expenses incurred by Dr. McDonald in connection with the patent applications and issued patents, (ii) pay Dr. McDonald $300,000 upon approval by the FDA of our first NDA incorporating BDP; (iii) pay Dr. McDonald royalty payments equal to 3% of net sales of the covered products and (iv) pay Dr. McDonald $400,000 in cash upon an approval of BDP by the European Medicines Agency.

Additionally, in the event that we sublicense our rights under the license agreement, we will be required to pay Dr. McDonald 10% of any sublicense fees and royalty payments paid by the sublicense to us.

The term of the license agreement expires upon the expiration of the licensed patent applications or patents. Dr. McDonald has the right to terminate the license agreement in its entirety or to terminate exclusivity under the agreement if we or its sublicenses have not commercialized or are not actively attempting to commercialize a covered product.

Additionally, the agreement terminates: (i) automatically upon us becoming insolvent; (ii) upon 30 days' notice, if we breach any obligation under the agreement without curing such breach during the notice period; and (iii) upon 90 days' notice by us. After any termination, we will have the right to sell our inventory for a period not to exceed three months following the date of termination, subject to the payment of the amounts owed under the agreement.

ThermoVax® License Agreement

On December 21, 2010, we executed a worldwide exclusive license agreement with the UC for ThermoVax®, which is the subject of U.S. patent number 8,444,991 issued on May 21, 2013 titled "Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition." This patent and its corresponding foreign filings are licensed to us by the UC and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. U.S. Patent 8,444,991 is expected to expire in December 2031. The license agreement also covers thermostable vaccines for biodefense as well as other potential vaccine indications. In addition, we, in conjunction with UC, filed domestic and foreign patent applications claiming priority back to a provisional application filed on May 17, 2011 titled: "Thermostable Vaccine Compositions and Methods of Preparing Same." In April 2018, the UC delivered a notice of termination of our license agreement based upon our failure to achieve one of the development milestones: initiation of the Phase 1 clinical trial of the heat stabilization technology by March 31, 2018. After negotiating with the UC, we and the UC agreed to extend the termination date to October 31, 2018 in order to allow us time to agree upon a potential agreement that would allow us to keep the rights to, and to continue to develop, the heat stabilization technology or a product candidate containing the heat stabilization technology in our field of use.

On October 31, 2018, in a series of related transactions, (a) we and the UC agreed to terminate the original license agreement, (b) the UC and VitriVax executed a worldwide exclusive license agreement for the heat stabilization technology for all fields of use, and (c) we and VitriVax executed a worldwide exclusive sublicense agreement, which was amended and restated in October 2020, for the heat stabilization technology for use in the fields of ricin and Ebola vaccines. We paid a $100,000 sublicense fee on the effective date of the sublicense agreement. Under the amended sublicense agreement to maintain the sublicense we are obliged to pay a minimum annual royalty of $20,000 until first commercial sale of a sublicensed product, upon which point, we will be required to pay an earned royalty of 2% of net sales subject to a minimum

royalty of $50,000 each year. We are also required to pay royalties on any sub-sublicense income based on a declining percentage of all sub-sublicense income calculated within the contractual period until reaching a minimum of 15% after two years. In addition, we are required to pay VitriVax milestone fees of: (a) $25,000 upon initiation of a Phase 2 clinical trial of the sublicensed product, (b) $100,000 upon initiation of a Phase 3 clinical trial of the sublicensed product, (c) $100,000 upon regulatory approval of a sublicensed product, and (d) $1 million upon achieving $10 million in aggregate net sales of a sublicensed product in the U.S. or equivalent. To date none of these milestones have been met.

RiVax® License Agreement

In June 2003, we executed a worldwide exclusive option to license patent applications with UTSW for the nasal, pulmonary and oral uses of a non-toxic ricin vaccine. In June 2004, we entered into a license agreement with UTSW for the injectable rights to the ricin vaccine and, in October 2004, we negotiated the remaining oral rights to the ricin vaccine. To maintain this license, we are obligated to pay $50,000 in annual license fees. Through this license, we have rights to the issued patent number 7,175,848 titled “Ricin A chain mutants lacking enzymatic activity as vaccines to protect against aerosolized ricin.” This patent includes methods of use and composition claims for RiVax®.

CoVaccine HT™ License Agreement

In April 2020, we executed an agreement for the exclusive worldwide license of CoVaccine HT™, a novel vaccine adjuvant, from BTG, a division of Boston Scientific Corporation (NYSE: BSX), for the fields of SARS-CoV-2, the cause of COVID-19 and pandemic flu. The agreement was executed with Protherics Medicines Development, one of the companies that make up the BTG specialty pharmaceuticals business, which owns the CoVaccine HT™ intellectual property.

Research and Development Expenditures

We spent approximately $7.9 million and $8.2 million in the years ended December 31, 2022 and 2021, respectively, on research and development. The amounts we spent on research and development per product during the years ended December 31, 2022 and 2021 are set forth in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report on Form 10-K.

Human Capital

We are committed to a work environment that is welcoming, inclusive and encouraging. To achieve our plans and goals, it is imperative that we attract and retain top talent. In order to do so, we aim to have a safe and encouraging workplace, with opportunities for our employees to grow and develop professionally, supported by strong compensation, benefits, and other incentives. In addition to competitive base salaries, we offer every full-time employee a cash target bonus, a comprehensive benefits package and equity compensation.

As of December 31, 2022, we employed a total of 15 persons, including 2 part-time employees and 13 full-time employees, five of whom are MDs/PhDs. In addition to our employees, we contract with third-parties for the conduct of certain clinical development, manufacturing, accounting and administrative activities. We anticipate increasing the number of our employees. We have no collective bargaining agreements with our employees, and none are represented by labor unions. We consider our relationships with our employees to be good.

Throughout the COVID 19 pandemic, many of our employees have worked remotely. In September 2021 our employees returned to the Company’s facilities in-person and have maintained a hybrid work schedule with both in-office and remote hours. We implemented a number of significant safety measures based on current guidelines recommended by the Centers for Disease Control. These include, but are not limited to, social distancing, capacity limitations, mask requirements in common areas, weekly deep cleaning and daily sanitation procedures.

Available Investor Information

We file electronically with the Securities and Exchange Commission (“SEC”) our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). We make available through our website, free of charge, copies of these reports as soon as reasonably practicable after we electronically file or

furnish them to the SEC. Our website is located at www.soligenix.com. You can also request copies of such documents by contacting the company at (609) 538-8200 or sending an email to info@soligenix.com.

Item 1A. Risk factors

An investment in our securities involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information about these risks contained in this Annual Report, as well as the other information contained in this Annual Report generally, before deciding to buy our securities. Any of the risks we describe below could adversely affect our business, financial condition, operating results or prospects. The market prices for our securities could decline if one or more of these risks and uncertainties develop into actual events and you could lose all or part of your investment. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in this Annual Report, including our financial statements and the related notes.

Summary of Risk Factors

Our business is subject to a number of risks and uncertainties that you should understand before making an investment decision. These risks include, but are not limited to, the following:

Risks Related to our Business

- We have had significant losses and anticipate future losses; if additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts or not be able to repay the Convertible Notes.

- Our losses from operations, negative cash flows, and shareholders' deficit as of December 31, 2022 as well as a projected potential breach of our cash debt covenant with our debt holder during the 12 month look-forward period from the issuance of the financial statements without taking additional measures, such as raising capital, raises substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings.

- The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, 2022 contains an explanatory paragraph relating to our ability to continue as a going concern.

- If we are unable to develop our product candidates, our ability to generate revenues and viability as a company will be significantly impaired.

- We have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all.

- Our business is subject to extensive governmental regulation, which can be costly, time consuming and subjects us to unanticipated delays.

- There may be unforeseen challenges in developing our biodefense products.

- We are dependent on government funding, which is inherently uncertain, for the success of our public health business segment operations.

- The terms of our loan and security agreement with Pontifax Medison Finance require, and any future debt financing may require, us to meet certain operating covenants and place restrictions on our operating and financial flexibility.

- If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products.

- If we are not able to maintain or secure agreements with third parties for pre-clinical and clinical trials of our product candidates on acceptable terms, if these third parties do not perform their services as required, or if these third

parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.

- The manufacturing of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

- We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

- Even if approved, our products will be subject to extensive post-approval regulation.

- Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market.

- We do not have extensive sales and marketing experience and our lack of experience may restrict our success in commercializing some of our product candidates.

- Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations.

- Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

- If we fail to obtain or maintain orphan drug exclusivity for our product candidates, our competitors may sell products to treat the same conditions and our revenue will be reduced.

- Federal and/or state health care reform initiatives could negatively affect our business.

- We may not be able to retain rights licensed to us by third parties to commercialize key products or to develop the third party relationships we need to develop, manufacture and market our products.

- We may suffer product and other liability claims; we maintain only limited product liability insurance, which may not be sufficient.

- We may use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly.

- We may not be able to compete with our larger and better-financed competitors in the biotechnology industry.

- Competition and technological change may make our product candidates and technologies less attractive or obsolete.

- Our business could be harmed if we fail to retain our current personnel or if they are unable to effectively run our business.

- Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations, and cash flows.

- Adverse developments affecting financial institutions such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

- We may not be able to utilize all of our net operating loss carryforwards.

- Global pathogens could have an impact on financial markets, materials sourcing, patients, governments and population (e.g. COVID-19).

Risks Related to our Intellectual Property

- We may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party.

- We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.

- If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

Risks Related to our Securities

- The price of our common stock may be highly volatile.

- If we fail to remain current with our listing requirements, we could be removed from The Nasdaq Capital Market, which would limit the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

- Shareholders may suffer substantial dilution related to issued stock warrants, options and convertible notes.

- Our shares of common stock are thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.

- We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

- Upon our dissolution, our stockholders may not recoup all or any portion of their investment.

- The issuance of our common stock pursuant to the terms of the asset purchase agreement with Hy Biopharma may cause dilution and the issuance of such shares of common stock, or the perception that such issuances may occur, could cause the price of our common stock to fall.

Risks Related to our Business

We have had significant losses and anticipate future losses; if additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts.

We have experienced significant losses since inception and, at December 31, 2022, had an accumulated deficit of approximately $219.6 million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of December 31, 2022, we had approximately $13.4 million in cash and cash equivalents available, and as of March 24, 2023 we had approximately $10.4 million in cash and cash equivalents available. Based on our projected budgetary needs, funding from existing contracts and grants over the next year and sales pursuant to our At Market Issuance Sales Agreement ("B. Riley Sales Agreement") with B. Riley Securities, Inc. ("B. Riley"), we expect to be able to maintain the current level of our operations into the third quarter of 2023.

In September 2014, we entered into a contract with the NIH for the development of RiVax® to protect against exposure to ricin toxin that would provide up to $24.7 million of funding in the aggregate over six years if options to extend the contract are exercised by the NIH. In 2017, we were awarded two separate grants from the NIH of approximately $1.5 million each to support our pivotal Phase 3 trials of HyBryte™ for the treatment of CTCL and SGX942 for the treatment of oral mucositis in head and neck cancer. In December 2020, we were awarded Direct to Phase II SBIR grant from NIAID of approximately $1.5 million to support manufacture, formulation (including thermostabilization) and characterization of COVID-19 and EVD vaccine candidates in conjunction with the CoVaccine HT™ adjuvant. Our biodefense grants have an overhead component

that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component associated with our existing contracts and grants will fund some fixed costs for direct employees working on these contracts and grants as well as other administrative costs. As of December 31, 2022, we had approximately $1.7 million in awarded grant funding available.

Our product candidates are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of these product candidates. From inception through December 31, 2022, we have expended approximately $116 million developing our current product candidates for pre-clinical research and development and clinical trials. We currently expect to spend approximately $3.7 million for the year ending December 31, 2023 in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements, of which approximately $0.7 million is expected to be reimbursed through our existing government contracts and grants.

We have no control over the resources and funding NIH, BARDA and NIAID may devote to our programs, which may be subject to periodic renewal and which generally may be terminated by the government at any time for convenience. Any significant reductions in the funding of U.S. government agencies or in the funding areas targeted by our business could materially and adversely affect our biodefense program and our results of operations and financial condition. If we fail to satisfy our obligations under the government contracts, the applicable Federal Acquisition Regulations allow the government to terminate the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the government any incomplete work. If NIH, BARDA or NIAID do not exercise future funding options under the contracts or grants, terminate the funding or fail to perform their responsibilities under the agreements or grants, it could materially impact our biodefense program and our financial results.

Unless and until we are able to generate sales or licensing revenue from one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations. If we cannot raise such additional funds, we may have to delay or stop some or all of our drug development programs.

Our losses from operations, negative cash flows, and shareholders' deficit as of December 31, 2022 as well as a projected potential breach of our cash debt covenant with our debt holder during the 12 month look-forward period from the issuance of the financial statements without taking additional measures, such as raising capital, raises substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings.

We have concluded that substantial doubt exists about our ability to continue as a going concern for the 12 months following the issuance of the financial statements included in this Annual Report on Form 10-K. As of December 31, 2022, we had cash and cash equivalents of $13.6 million and current liabilities of $16.5 million. As of the issuance date of these financial statements, we believe that we have sufficient resources available to support our development activities and business operations and timely satisfy our obligations as they come due into the third quarter of 2023. We do not have sufficient cash and cash equivalents as of the date of filing this Annual Report on Form 10-K to support our operations for at least the 12 months following the issuance of the financial statements.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to secure additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations, securing additional proceeds from government contract and grant programs, securing additional proceeds available from the sale of shares of our common stock via the B. Riley Sales Agreement with B. Riley and potentially amending the loan agreement with Pontifax to reduce the conversion price in order to allow for conversion of a portion of the debt which will reduce our accounts payable; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, identify and enter into any strategic transactions that will provide the capital that we will require or achieve the other strategies to alleviate the conditions that raise substantial doubt about our ability to continue as a going concern. If none of these alternatives are available, or if available, are not available on satisfactory terms, we will not have sufficient cash resources and liquidity to fund our business operations for at least the 12 months following the date the financial statements are issued. The failure to obtain sufficient capital on acceptable terms

when needed may require us to delay, limit, or eliminate the development of business opportunities and our ability to achieve our business objectives and our competitiveness, and our business, financial condition, and results of operations will be materially adversely affected. In addition, market instability, including as a result of geopolitical instability, may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. In addition, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, 2022 contains an explanatory paragraph relating to our ability to continue as a going concern.

The auditor's opinion on our audited financial statements for the year ended December 31, 2022 includes an explanatory paragraph stating that we have incurred recurring losses from operations that raise substantial doubt about our ability to continue as a going concern. While we believe that we will be able to obtain the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, we would need to significantly reduce our operating plans and curtail some or all of our development efforts. Accordingly, our business, prospects, financial condition, and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

If we are unable to develop our product candidates, our ability to generate revenues and viability as a company will be significantly impaired.

In order to generate revenues and profits, our organization must, along with corporate partners and collaborators, positively research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of clinical and pre-clinical development and will require significant further funding, research, development, pre-clinical and/or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our product candidates:

- we may not be able to maintain our current research and development schedules;
- we may be unable to secure procurement contracts on beneficial economic terms or at all from the U.S. government or others for our biodefense products;
- we may encounter problems in clinical trials; or
- the technology or product may be found to be ineffective or unsafe, or may fail to obtain marketing approval.

If any of the risks set forth above occur, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may be unable to develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to commercialize or receive royalties from the sale of any other technology we develop, even if it is shown to be effective, if:

- it is not economical or the market for the product does not develop or diminishes;
- we are not able to enter into arrangements or collaborations to manufacture and/or market the product;
- the product is not eligible for third-party reimbursement from government or private insurers;
- others hold proprietary rights that preclude us from commercializing the product;
- we are not able to manufacture the product reliably;
- others have brought to market similar or superior products; or

- the product has undesirable or unintended side effects that prevent or limit its commercial use.

We expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a late-stage biopharmaceutical company. Our operations to date have been primarily limited to developing our technology and undertaking pre-clinical studies and clinical trials of our product candidates in our two active business segments, Specialized BioTherapeutics and Public Health Solutions. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this Annual Report and also include:

- our ability to obtain additional funding to develop our product candidates;
- our ability to repay existing debt in accordance with its terms;
- delays in the commencement, enrollment and timing of clinical trials;
- the success of our product candidates through all phases of clinical development;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to obtain and maintain regulatory approval for our product candidates in the U.S. and foreign jurisdictions;
- potential side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies, or cause an approved drug to be taken off the market;
- our dependence on third-party contract manufacturing organizations to supply or manufacture our products;
- our dependence on contract research organizations to conduct our clinical trials;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- market acceptance of our product candidates;
- our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to build our finance infrastructure and improve our accounting systems and controls;
- potential product liability claims;

- potential liabilities associated with hazardous materials; and

- our ability to obtain and maintain adequate insurance policies.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

We have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all.

To date, we have no approved product on the market and have not generated any significant product revenues. We have funded our operations primarily from sales of our securities and from government contracts and grants. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential or successfully obtain government procurement or stockpiling agreements. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

Our business is subject to extensive governmental regulation, which can be costly, time consuming and subjects us to unanticipated delays.

Our business is subject to very stringent federal, foreign, state and local government laws and regulations, including the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these acts. These laws and regulations may be amended, additional laws and regulations may be enacted, and the policies of the FDA and other regulatory agencies may change.

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years, is uncertain as to outcome, and requires the expenditure of substantial capital and other resources. We estimate that the clinical trials of our product candidates that we have planned will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Favorable results in early studies or trials, if any, may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing, Phase 1 and Phase 2 clinical trials does not ensure that later Phase 2 or Phase 3 clinical trials will be successful. In addition, we, the FDA or other regulatory authorities may suspend clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or the FDA or other regulatory authorities find deficiencies in our submissions or conduct of our trials.

We may not be able to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product (for example, the FDA may not recognize fast track designation upon an NDA submission, resulting in no priority review and subjecting us to longer potential review times than originally anticipated). Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed.

Following any regulatory approval, a marketed product and its manufacturer are subject to continual regulatory review. Later discovery of problems with a product or manufacturer may result in restrictions on such product or manufacturer. These restrictions may include product recalls and suspension or withdrawal of the marketing approval for the product. Furthermore, the advertising, promotion and export, among other things, of a product are subject to extensive regulation by governmental authorities in the U.S. and other countries. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and/or criminal prosecution.

There may be unforeseen challenges in developing our biodefense products.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans, referred to as the Animal Rule. However, we will still have to establish that the vaccines we are

developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the Animal Rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasures for bioterrorism agents. Despite the Animal Rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations. The government's biodefense priorities can change, which could adversely affect the commercial opportunity for the products we are developing. Further, other countries have not, at this time, established criteria for review and approval of these types of products outside their normal review process, i.e., there is no Animal Rule equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

Additionally, few facilities in the U.S. and internationally have the capability to test animals with ricin, or otherwise assist us in qualifying the requisite animal models. We have to compete with other biodefense companies for access to this limited pool of highly specialized resources. We therefore may not be able to secure contracts to conduct the testing in a predictable timeframe or at all.

We are dependent on government funding, which is inherently uncertain, for the success of our biodefense operations.

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments. Our receipt of government funding is also dependent on our ability to adhere to the terms and provisions of the original grant and contract documents and other regulations. We can provide no assurance that we will receive or continue to receive funding for grants and contracts we have been awarded. The loss of government funds could have a material adverse effect on our ability to progress our biodefense business.

The terms of our loan and security agreement with Pontifax Medison Finance require, and any future debt financing may require, us to meet certain operating covenants and place restrictions on our operating and financial flexibility.

In December 2020, we entered into a loan and security agreement with Pontifax Medison Finance (the "Loan and Security Agreement"), that is secured by a lien covering substantially all of our assets, other than our intellectual property and licenses for intellectual property. The Loan and Security Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to protect and maintain our intellectual property and comply with all applicable laws, deliver certain financial reports, maintain a minimum cash balance and maintain insurance coverage. Negative covenants include, among others, covenants restricting us from transferring any material portion of our assets, incurring additional indebtedness, engaging in mergers or acquisitions, changing foreign subsidiary voting rights, repurchasing shares, paying dividends or making other distributions, making certain investments, and creating other liens on our assets, including our intellectual property, in each case subject to customary exceptions. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. These restrictions may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. If we default under the terms of the Loan and Security Agreement or any future debt facility, the lender may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our common stock. The lender could declare a default upon the occurrence of any event that it interprets as a material adverse effect as defined under the Loan and Security Agreement or based upon

our insolvency. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products. We do not have or anticipate having internal manufacturing capabilities.

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards, which material will be used in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to be able to develop, produce, secure regulatory approval of and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

We rely on third parties for pre-clinical and clinical trials of our product candidates and, in some cases, to maintain regulatory files for our product candidates. If we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.

We rely on academic institutions, hospitals, clinics and other third-party collaborators for preclinical and clinical trials of our product candidates. Although we monitor, support, and/or oversee our pre-clinical and clinical trials, because we do not conduct these trials ourselves, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then preclinical and/or clinical trials of our product candidates may be extended, delayed or terminated, or our data may be rejected by the FDA or regulatory agencies.

The manufacturing of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with current Good Manufacturing Practice (“cGMP”) or similar requirements that the FDA or foreign regulators establish. We, or our materials suppliers, may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA’s cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we are currently focusing on the regulatory approval of certain product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on existing and future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in an area in which it would have been more advantageous to enter into a partnering arrangement.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval.

Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market.

Even if the FDA approves one or more of our product candidates, physicians and patients may not accept it or use it. Even if physicians and patients would like to use our products, our products may not gain market acceptance among healthcare payors such as managed care formularies, insurance companies or government programs such as Medicare or Medicaid. Acceptance and use of our products will depend upon a number of factors including: perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug product; cost-effectiveness of our product relative to competing products; availability of reimbursement for our product from government or other healthcare payers; and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The degree of market acceptance of any product that we develop will depend on a number of factors, including:

- cost-effectiveness;
- the safety and effectiveness of our products, including any significant potential side effects, as compared to alternative products or treatment methods;
- the timing of market entry as compared to competitive products;
- the rate of adoption of our products by doctors and nurses;
- product labeling or product insert required by the FDA for each of our products;
- reimbursement policies of government and third-party payors;

- effectiveness of our sales, marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners, if any; and

- unfavorable publicity concerning our products or any similar products.

Our product candidates, if successfully developed, will compete with a number of products manufactured and marketed by major pharmaceutical companies, biotechnology companies and manufacturers of generic drugs. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept and utilize any of our product candidates. If our products do not achieve market acceptance, we will not be able to generate significant revenues or become profitable.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and could require us to seek additional financing.

We do not have extensive sales and marketing experience and our lack of experience may restrict our success in commercializing some of our product candidates.

We do not have extensive experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. To obtain the expertise necessary to successfully market and sell any of our products, the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships will be required. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract.

Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations.

Initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Serious adverse events or undesirable side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The results of future clinical trials may show that our product candidates cause serious adverse events or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities.

If any of our product candidates cause serious adverse events or undesirable side effects:

- regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product;

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;
- we may be required to limit the patients who can receive the product;
- we may be subject to limitations on how we promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

If we fail to obtain or maintain orphan drug exclusivity for our product candidates, our competitors may sell products to treat the same conditions and our revenue will be reduced.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the EU, the European Medicines Agency's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have orphan drug designation for HyBryte™ in the U.S. and Europe, and SGX203, RiVax® in the U.S., we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing drugs or biologic products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Absent patent or other intellectual property protection, even after an orphan drug is approved, the FDA or European Medicines Agency may subsequently approve the same drug with the same active moiety

for the same condition if the FDA or European Medicines Agency concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

Federal and/or state health care reform initiatives could negatively affect our business.

The availability of reimbursement by governmental and other third-party payers affects the market for any pharmaceutical product. These third-party payers continually attempt to contain or reduce the costs of healthcare. There have been a number of legislative and regulatory proposals to change the healthcare system and further proposals are likely. Medicare's policies may decrease the market for our products. Significant uncertainty exists with respect to the reimbursement status of newly approved healthcare products.

Third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Once approved, we might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates addressing small patient populations. On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms to establish a bundled Medicare payment rate that includes services and drug/labs that were separately billed at that time. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. We expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

We may not be able to retain rights licensed to us by third parties to commercialize key products or to develop the third party relationships we need to develop, manufacture and market our products.

We currently rely on license agreements from New York University, Yeda Research and Development Company Ltd., the University of Texas Southwestern Medical Center, the University of British Columbia, and George B. McDonald, MD as well as sublicense agreement from VitriVax for the rights to commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, if at all. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license.

Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates. See "Business – Patents and Other Proprietary Rights" for a description of our license agreements.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and

- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Additionally, the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract or partner with outside researchers, in most cases with or through those parties that did the original research and from whom we have licensed the technologies. If products are successfully developed and approved for commercialization, then we will need to enter into additional collaboration and other agreements with third parties to manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or preclude the development, manufacture and/or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights may limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products.

Additionally, if we do not enter into relationships with additional third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force or enter into commercialization agreements with other companies. Development of an effective sales force in any part of the world would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved.

We may suffer product and other liability claims; we maintain only limited product liability insurance, which may not be sufficient.

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with aggregate limits of liability of $10 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

We may use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly.

Our research and development processes and/or those of our third party contractors involve the controlled use of hazardous materials and chemicals. These hazardous chemicals are reagents and solvents typically found in a chemistry laboratory. Our operations also may produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. While we attempt to comply with all environmental laws and regulations, including those relating to the outsourcing of the disposal of all hazardous chemicals and waste

products, we cannot eliminate the risk of contamination from or discharge of hazardous materials and any resultant injury. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations.

Compliance with environmental laws and regulations may be expensive. Current or future environmental regulations may impair our research, development or production efforts. We might have to pay civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. We are not insured against these environmental risks. We may agree to indemnify our collaborators in some circumstances against damages and other liabilities arising out of development activities or products produced in connection with these collaborations.

In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

We may not be able to compete with our larger and better financed competitors in the biotechnology industry.

The biotechnology industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Most of our existing competitors have greater financial resources, larger technical staffs, and larger research budgets than we have, as well as greater experience in developing products and conducting clinical trials. Our competition is particularly intense in the gastroenterology and transplant areas and is also intense in the therapeutic area of inflammatory bowel diseases. We face intense competition in the biodefense area from various public and private companies and universities as well as governmental agencies, such as the U.S. Army, which may have their own proprietary technologies that may directly compete with our technologies. In addition, there may be other companies that are currently developing competitive technologies and products or that may in the future develop technologies and products that are comparable or superior to our technologies and products. We may not be able to compete with our existing and future competitors, which could lead to the failure of our business.

Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non-patent exclusivity and/or the listing with the FDA by the competitor of patents covering its newly-approved drug product. Periods of non-patent exclusivity for new versions of existing drugs such as our current product candidates can extend up to three and one-half years. See “Business – The Drug Approval Process.”

These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to commercialize products and achieve revenue and profits.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than us, obtaining FDA approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

There can be no assurance that any of our product candidates will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors’ products are approved before ours, it could be more difficult for us to obtain approval from the FDA. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept our product(s) as a treatment of choice.

Furthermore, the pharmaceutical research industry is diverse, complex, and rapidly changing. By its nature, the business risks associated therewith are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA regulations preclude us from forecasting revenues or income with certainty or even confidence.

Our business could be harmed if we fail to retain our current personnel or if they are unable to effectively run our business.

We currently have 15 employees and we depend upon these employees, in particular Dr. Christopher Schaber, our President and Chief Executive Officer, to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. We may be unable to effectively manage and operate our business, and our business may suffer, if we lose the services of our employees.

Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations, and cash flows.

During recent years, there has been substantial volatility in financial markets due at least in part to the uncertainty with regard to the global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by current and future economic conditions. These conditions could have an adverse effect on our industry and business, including our financial condition, results of operations, and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to issue stock or incur indebtedness to finance our plans for growth. Recent turmoil in the credit markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through borrowings, under either existing or newly created instruments in the public or private markets on terms we believe to be reasonable, if at all.

Adverse developments affecting financial institutions such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the "FDIC") as receiver. Despite subsequent actions taken by the U.S. Department of the Treasury, the U.S. Federal Reserve and the FDIC to ensure that all depositors of SVB had access to all of their cash deposits following the closure of SVB, uncertainty and liquidity concerns in the broader financial services industry remain.

We maintain cash balances at a third-party financial institution in excess of the FDIC insurance limit. Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired to the extent the financial institution with which we maintain cash balances faces liquidity constraints or failures. Any material decline in our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in significant disruptions to our business, any of which could have material adverse impacts on our operations and liquidity. There is no guarantee that the U.S. Department of Treasury, the U.S. Federal Reserve and the FDIC will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all.

We may not be able to utilize all of our net operating loss carryforwards.

The State of New Jersey's Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused net operating loss ("NOL") carryforwards to other New Jersey-based corporate taxpayers. We sold 2020 and 2019 New Jersey NOL carryforwards, resulting in the recognition of $1,154,935 and $864,742 of income tax benefit, net of transaction costs during the years ended December 31, 2022 and 2021, respectively. We sold our 2021 New Jersey NOL carryforwards and received $1,161,197, net of transaction costs, in January 2023, which will be recognized in the first quarter of 2023. We have not yet sold our 2022 New Jersey NOL carryforwards but may do so in the future. If there is an unfavorable change in the State of New Jersey's Technology Business Tax Certificate Program (whether as a result of a change in law, policy or otherwise) that terminates the program or eliminates or reduces our ability to use or sell our

NOL carryforwards or if we are unable to find a suitable buyer to utilize our New Jersey NOL carryforwards to the extent the NOLs expire before we are able to utilize them against our taxable income, our cash taxes may increase which may have an adverse effect on our financial condition.

Global pathogens that could have an impact on financial markets, materials sourcing, patients, governments and population (e.g. COVID-19).

Based on the current outbreak of the Coronavirus SARS-CoV-2, the pathogen responsible for COVID-19, which has already had an impact on financial markets, there could be additional repercussions to our operating business, including but not limited to, the sourcing of materials for our product candidates, manufacture of supplies for our preclinical and/or clinical studies, delays in clinical operations, which may include the availability or the continued availability of patients for our trials due to such things as quarantines, our conduct of patient monitoring and clinical trial data retrieval at investigational study sites.

The future impact of the outbreak is highly uncertain and cannot be predicted, and we cannot provide any assurance that the outbreak will not have a material adverse impact on our operations or future results or filings with regulatory health authorities. The extent of the impact to us, if any, will depend on future developments, including actions taken to contain the coronavirus.

Risks Related to our Intellectual Property

We may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party.

Our near and long-term prospects depend in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor.

Although we and our licensors have filed various patent applications covering the uses of our product candidates, patents may not be issued from the patent applications already filed or from applications that we might file in the future. Moreover, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and has been the subject of much litigation. Any patents we own or license, now or in the future, may be challenged, invalidated or circumvented. To date, no consistent policy has been developed in the U.S. Patent and Trademark Office (the “PTO”) regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the U.S. are maintained in secrecy until patent applications publish or patents issue, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we and our licensors are the first creators of inventions covered by any licensed patent applications or patents or that we or they are the first to file. The PTO may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned or licensed to us may not be valid or may not afford us protection against competitors with similar technology, and the patent applications licensed to us may not result in the issuance of patents.

It is also possible that our owned and licensed technologies may infringe on patents or other rights owned by others, and licenses to which may not be available to us. We may be unable to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

In addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.

The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

Competitors may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly.

Also, a third party may assert that our patents are invalid and/or unenforceable. There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation could result in inadequate protection for our product candidates and/or reduce the value of any license agreements we have with third parties.

Interference proceedings brought before the PTO may be necessary to determine priority of invention with respect to our patents or patent applications. During an interference proceeding, it may be determined that we do not have priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference proceeding may result in substantial costs and distraction to our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the price of our common stock could be adversely affected.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product candidate; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Risks Related to our Securities

The price of our common stock may be highly volatile.

The market price of our securities, like that of many other research and development public pharmaceutical and biotechnology companies, has been highly volatile and the price of our common stock may be volatile in the future due to a wide variety of factors, including:

- announcements by us or others of results of pre-clinical testing and clinical trials;
- announcements of technological innovations, more important bio-threats or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- failure of our common stock to continue to be listed or quoted on a national exchange or market system, such as The Nasdaq Stock Market ("Nasdaq") or NYSE Amex LLC;
- our quarterly operating results and performance;
- developments or disputes concerning patents or other proprietary rights;
- mergers or acquisitions;
- litigation and government proceedings;
- adverse legislation;
- changes in government regulations;
- our available working capital;
- economic and other external factors; and
- general market conditions.

Since January 1, 2022, the closing stock price of our common stock has fluctuated between a high of $15.00 per share to a low of $5.70 per share. On March 24, 2023, the last reported sales prices of our common stock on The Nasdaq Capital Market was $1.84 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of common stock and warrants by us, as well as potential sale of common stock by the holders of warrants and options, could have an adverse effect on the market price of our shares.

If we fail to remain current with our listing requirements, we could be removed from The Nasdaq Capital Market, which would limit the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

Companies trading on The Nasdaq Stock Market, such as our Company, must be reporting issuers under Section 12 of the Exchange Act, as amended, and must meet the listing requirements in order to maintain the listing of common stock on The Nasdaq Capital Market. If we do not meet these requirements, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

On December 20, 2021, we received a written notice (the "Bid Price Notice") from the Listing Qualifications department of Nasdaq indicating that we were not in compliance with the $1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market (the "Minimum Bid Price Requirement"). The notification of noncompliance had no immediate effect on the listing or trading of our common stock on The Nasdaq Capital Market.

On June 21, 2022, we delivered to the Listing Qualifications Department of Nasdaq a confidential plan to regain compliance with the Minimum Bid Price Requirement, which included upcoming important milestones such as the submission of new drug application for HyBryte™ in the treatment of cutaneous T-cell lymphoma and the initiation of a Phase 2 psoriasis clinical trial. On June 22, 2022, the Listing Qualifications Department of Nasdaq sent us a second notice, indicating that we were eligible for an additional 180 period, or until December 19, 2022, in which to regain compliance. Additionally, on November 16, 2022, Nasdaq notified us that we no longer complied with the continued listing requirement to maintain a minimum of $2,500,000 in shareholders' equity nor did we meet the alternatives of market value of listed securities or net income from continuing operations (the "Shareholders' Equity Requirement").

We were unable to regain compliance with the Minimum Bid Price Requirement prior to the expiration of the second 180 calendar day period. On December 20, 2022, we received written notice (the "Notice") from Nasdaq stating that we had not complied with the Minimum Bid Price Requirement or the Shareholders' Equity Requirement. The Notice indicated that our common stock would be suspended from trading on Nasdaq unless we requested a hearing before a hearings panel by December 27, 2022. We timely requested a hearing, which stayed any trading suspension of our common stock until completion of the Nasdaq hearing process and expiration of any additional extension period granted by the panel following the hearing. In advance of the hearing, we provided the Nasdaq Hearings Panel (the "Panel") with our plan to regain compliance. The appeal was heard by the Panel on February 2, 2023.

At a special meeting of stockholders held on February 8, 2023, our stockholders granted our Board of Directors the discretion to effect a reverse stock split of our common stock through an amendment to our Second Amended and Restated Certificate of Incorporation at a ratio of not less than 1-for-2 and not more than 1-for-20, with such ratio to be determined by our Board of Directors. We effected a reverse stock split of our common stock at a ratio of 1 post-split share for every 15 pre-split shares on Thursday, February 9, 2023. Our common stock continued to be traded on The Nasdaq Capital Market under the symbol SNGX and began trading on a split-adjusted basis when the market opened on Friday, February 10, 2023.

On February 21, 2023, we received a letter (the "Continued Listing Letter") from Nasdaq, stating that the Panel granted our request to continue listing on Nasdaq, on the condition that (1) on February 24, 2023, we shall have demonstrated compliance with the Minimum Bid Price Requirement, by evidencing a closing bid price of $1.00 or more per share for a minimum of ten consecutive trading sessions; and (2) on or before March 31, 2023, we shall demonstrate compliance with the Shareholders' Equity Requirement.

As of the close of the market on February 24, 2023, we satisfied the first condition – compliance with the Minimum Bid Price Requirement for a minimum of ten consecutive trading sessions.

We have requested an extension of the time by which we must regain compliance with the Shareholders' Equity Requirement. There can be no assurance that we will be able to regain compliance with the Shareholders' Equity Requirement prior to any extended deadline established by Nasdaq or at all, that Nasdaq will grant us an extension of time to achieve such compliance or that our common stock will remain listed on The Nasdaq Capital Market.

Shareholders may suffer substantial dilution related to issued stock warrants, options and convertible notes.

As of December 31, 2022, we had a number of agreements or obligations that may result in dilution to investors. These include:

- warrants to purchase a total of approximately 667 shares of our common stock at a current weighted average exercise price of $29.25;

- options to purchase approximately 192,273 shares of our common stock at a current weighted average exercise price of $27.56;

- the B. Riley Sales Agreement pursuant to which we may, but have no obligation to, sell up to an additional $26.6 million worth of our common stock as of March 24, 2023, subject to the limitations imposed by General Instruction I.B.6 to Form S-3; and

- convertible promissory notes issued to Pontifax Medison Finance, which may be converted into up to 162,602 shares of common stock at a price of $61.50 per share under the initial loan borrowing of $10 million.

We also have an incentive compensation plan for our management, employees and consultants. We have granted, and expect to grant in the future, options to purchase shares of our common stock to our directors, employees and consultants. To the extent that warrants or options are exercised, our stockholders will experience dilution and our stock price may decrease.

Additionally, the sale, or even the possibility of the sale, of the shares of common stock underlying these warrants and options could have an adverse effect on the market price for our securities or on our ability to obtain future financing.

Our shares of common stock are thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.

Our common stock has from time to time been "thinly-traded," meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we become more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, our stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

Upon our dissolution, our stockholders may not recoup all or any portion of their investment.

In the event of our liquidation, dissolution or winding-up, whether voluntary or involuntary, the proceeds and/or our assets remaining after giving effect to such transaction, and the payment of all of our debts and liabilities will be distributed to the holders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up. In this event, our stockholders could lose some or all of their investment.

The issuance of our common stock pursuant to the terms of the asset purchase agreement with Hy Biopharma Inc. may cause dilution and the issuance of such shares of common stock, or the perception that such issuances may occur, could cause the price of our common stock to fall.

On April 1, 2014, we entered into an option agreement pursuant to which Hy Biopharma granted us an option to purchase certain assets, properties and rights (the "Hypericin Assets") related to the development of Hy Biopharma's synthetic hypericin product candidate for the treatment of CTCL, which we refer to as HyBryte™, from Hy Biopharma. In exchange for the option, we paid $50,000 in cash and issued 288 shares of common stock in the aggregate to Hy Biopharma and its assignees. We subsequently exercised the option, and on September 3, 2014, we entered into an asset purchase agreement with Hy Biopharma, pursuant to which we purchased the Hypericin Assets. Pursuant to the purchase agreement, we initially paid $275,000 in cash and issued 12,328 shares of common stock in the aggregate to Hy Biopharma and its assignees, and the licensors of the license agreement acquired from Hy Biopharma. Also, on September 3, 2014, we entered into a Registration Rights Agreement with Hy Biopharma, pursuant to which we may be required to file a registration statement with the SEC. In March 2020, we issued 130,413 shares of common stock at a value of $5,000,000 (based upon an effective per share price of $38.40 as a result of HyBryte™ demonstrating statistically significant treatment response in the Phase 3 clinical trial. We will be required to issue up to $5.0 million worth of our common stock (subject to a cap equal

to 19.9% of our issued and outstanding common stock) in the aggregate, if HyBryte™ is approved for the treatment of CTCL by either the FDA or the EMA.

The number of shares that we may issue under the purchase agreement will fluctuate based on the market price of our common stock. Depending on market liquidity at the time, the issuance of such shares may cause the trading price of our common stock to fall.

We may ultimately issue all, some or none of the additional shares of our common stock that may be issued pursuant to the purchase agreement. We are required to register any shares issued pursuant to the purchase agreement for resale under the Securities Act of 1933, as amended (the "Securities Act"). After any such shares are registered, the holders will be able to sell all, some or none of those shares. Therefore, issuances by us under the purchase agreement could result in substantial dilution to the interests of other holders of our common stock. Additionally, the issuance of a substantial number of shares of our common stock pursuant to the purchase agreement, or the anticipation of such issuances, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

Repayment of certain convertible notes, if they are not otherwise converted, will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on our indebtedness.

Our ability to pay the principal of and/or interest on the convertible notes issued pursuant to the Loan and Security Agreement with Pontifax Medison Finance (the "Convertible Notes") depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service the Convertible Notes or other future indebtedness and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt and implement one or more alternatives, such as selling assets, restructuring indebtedness or obtaining additional debt financing or equity financing on terms that may be onerous or highly dilutive. Our ability to refinance the Convertible Notes or other future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including the Convertible Notes.

The issuance of shares of common stock upon conversion of the Convertible Notes could substantially dilute shareholders' investments and could impede our ability to obtain additional financing.

The Convertible Notes are convertible into shares of our common stock and give the holders an opportunity to profit from a rise in the market price of our common stock such that conversion or exercise thereof could result in dilution of the equity interests of our shareholders. We have no control over whether the holders will exercise their right to convert their Convertible Notes. While the Convertible Notes are convertible at a minimum price of $61.50 per share which is higher than our current market price, we cannot predict the market price of our common stock at any future date, and therefore, cannot predict whether the Convertible Notes will be converted. We may also choose to reduce the conversion price of the Convertible Notes in order to reduce our accounts payable, which would likely cause the Convertible Notes to be convertible into a significant amount of our common stock. The existence and potentially dilutive impact of the Convertible Notes may prevent us from obtaining additional financing in the future on acceptable terms, or at all.

Our Board of Directors can, without stockholder approval, cause preferred stock to be issued on terms that adversely affect holders of our common stock.

Under our Certificate of Incorporation, our Board of Directors is authorized to issue up to 230,000 shares of preferred stock, of which none are issued and outstanding as of the date of this prospectus. Also, our Board of Directors, without stockholder approval, may determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares. If our Board of Directors causes shares of preferred stock to be issued, the rights of the holders of our common stock would likely be subordinate to those of preferred holders and therefore could be adversely affected. Our Board of Directors' ability to determine the terms of preferred stock and to cause its issuance, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire a majority of our outstanding common stock. Preferred shares issued by our Board of Directors could include voting rights or super voting rights, which could shift the ability to control the Company to the holders of the preferred stock. Preferred stock could also have conversion rights into shares of our common stock at a discount to the market price of our common stock, which could negatively affect the market for our common stock. In addition, preferred stock would have

preference in the event of liquidation of the corporation, which means that the holders of preferred stock would be entitled to receive the net assets of the corporation distributed in liquidation before the holders of our common stock receive any distribution of the liquidated assets.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 6,200 square feet of office space at 29 Emmons Drive, Suite B-10 in Princeton, New Jersey. This office space currently serves as our corporate headquarters, and both of our business segments (Specialized BioTherapeutics and Public Health Solutions), operate from this space. Pursuant to an amendment on June 21, 2022, the lease has been extended from November 2022 to October 2025. The current rent is approximately $11,108 per month and will remain so through October 2023. The rent for lease periods starting November 2023 and November 2024 is approximately $11,367 per month and $11,625 per month, respectively. Our office space is sufficient for our current needs. We may add new space or expand existing space as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 3. Legal Proceedings

From time to time, we are a party to claims and legal proceedings arising in the ordinary course of business. Our management evaluates our exposure to these claims and proceedings individually and in the aggregate and allocates additional monies for potential losses on such litigation if it is possible to estimate the amount of loss and if the amount of the loss is probable.

In July 2020, we filed a demand for arbitration against Emergent BioSolutions, Inc. (“EBS”); Emergent Product Development Gaithersburg, Inc. (“EPDG”); and Emergent Manufacturing Operations Baltimore LLC (“EMOB” and, together with EBS and EPDG, “Emergent”) with the American Arbitration Association in Mercer County, New Jersey in which we have alleged that (a) EPDG breached the EPDG Subcontract (defined in the following paragraph), the EPDG Quality Agreement (defined in the following paragraph), an express warranty, a warranty of merchantability, and a warranty of fitness for a particular purpose, (b) EMOB breached the EMOB Quality Agreement (defined in the following paragraph); (c) EPDG was unjustly enriched; (d) EPDG and EMOB were negligent in the performance of their work; and (e) EBS fraudulently induced us into entering into the contracts with EPDG and EMOB. Emergent has answered that demand for arbitration denying the allegations and asserting affirmative defenses. The arbitration arose as a result of the following:

After several months of negotiations and based on representations Emergent made related to its capabilities in developing upstream and downstream processes for vaccines and its designation as a Center for Innovation in Advanced Development and Manufacturing, in May 2015, we entered into a subcontract (the “EPDG Subcontract”) with EPDG, pursuant to which EPDG agreed to manufacture, and provide to us, RiVax® bulk drug substance (“BDS”). In March 2017, we entered into a quality agreement (the “EPDG Quality Agreement”) with EPDG for the purpose of defining and allocating the quality-related responsibilities between EPDG and us with respect to the production of the RiVax® BDS under the EPDG Subcontract.

After nearly three years of EPDG failing to meet the scope of work set forth in the EPDG Subcontract, Emergent recommended that both development and manufacturing work under the EPDG Subcontract be transferred to EMOB. In July 2018, we entered into a quality agreement (the “EMOB Quality Agreement”) with EMOB, which agreement allocated various defined responsibilities between EMOB and us with respect to the manufacture, supply, and testing of the RiVax® BDS. Under the EMOB Quality Agreement, EMOB assumed sole responsibility for, inter alia, (i) employee training; (ii) providing adequate and qualified personnel; (iii) notifying us of out-of-specification results within two (2) business days of identification of the out of-specification results; (iv) performing testing using agreed-to testing procedures, test methods, specifications, and required compendia requirements; (v) ensuring that EMOB-generated data was accurate, controlled and safe from manipulation or loss; (vi) ensuring that the procedures, the state of automation and/or management controls were in place to assure data integrity; (vii) apprising us of any significant changes to analytical methodology for intermediaries, in-process or final product; and (viii) assuring that samples were stored in appropriate, continuously monitored conditions.

In January 2020, EMOB informed us (a) of the existence of a questionable test result that could result in a determination that the RiVax® BDS manufactured, tested and released by EMOB was out-of-specification and should never have been

released by Emergent (b) that the validity of "initial release" test results for such BDS was faulty because Emergent used an improper test method. We immediately suspended the Phase 1c trial to evaluate RiVax® in healthy adults, ending both further enrollment and further dosing. Emergent conducted an internal review of this deviation and found multiple internal failures including an "Inadequate analytical method transfer process," an "Inability to comply with standard operating procedures around method transfer and data review," and an "Inability to comply with test method procedures," We quickly initiated a "for-cause" audit of the Emergent facility and confirmed the failures Emergent identified and admitted to in its own internal investigation.

We sought to recover damages in excess of $19 million from Emergent. We presented our case at an arbitration hearing over 12 days in January 2022. Following submission of post-hearing briefs, the arbitration panel heard closing oral arguments in April 2022. On July 6, 2022, the American Arbitration Association entered a final decision in connection with this arbitration. Despite the arbitration panel ruling that Emergent had committed a number of breaches of the parties' contracts, the panel did not award monetary damages to us. On September 30, 2022, we filed a petition to vacate the arbitration decision with the Delaware Court of Chancery, requesting that the Court vacate the arbitration decision and remand the matter to the arbitration panel for rehearing. We cannot offer any assurances as to any result of our challenge of the arbitration decision or that we will recover any damages from Emergent.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on The Nasdaq Capital Market under the symbol "SNGX." The following table sets forth the high and low sales prices per share of our common stock for the periods indicated, as reported by The Nasdaq Capital Market.

	Price Range	
Period	**High**	**Low**
Year Ended December 31, 2021:		
First Quarter	$ 37.20	$ 18.90
Second Quarter	$ 24.30	$ 12.90
Third Quarter	$ 19.80	$ 12.75
Fourth Quarter	$ 16.80	$ 10.20
Year Ended December 31, 2022:		
First Quarter	$ 13.65	$ 8.70
Second Quarter	$ 12.00	$ 5.70
Third Quarter	$ 15.00	$ 6.45
Fourth Quarter	$ 10.95	$ 5.85

On March 24, 2023, the last reported price of our common stock quoted on The Nasdaq Capital Market was $1.84 per share. The Nasdaq Capital Market prices set forth above represent inter-dealer quotations, without adjustment for retail mark-up, mark-down or commission, and may not represent the prices of actual transactions. Our stock is listed on The Nasdaq Capital Market under the under the symbol "SNGX." On December 13, 2016, certain of our common stock warrants began trading on The Nasdaq Capital Market under the symbol "SNGXW." These tradable warrants expired on December 15, 2021. For the period from January 1, 2021 through December 15, 2021, the high and low sales price per warrant as reported by Nasdaq were $9.75 and $0.15 respectively.

Unregistered Sales of Equity Securities

We issued a vendor 1,667 shares of fully vested common stock with a fair value of $7.20 per share on October 4, 2022. We also issued a vendor 5,129 shares of fully vested common stock with a fair value of $9.75 per share on November 7, 2022.

The issuances of common stock to the vendors as described above were exempt under Section 4(a)(2) of the Securities Act of 1933, as amended. The vendors are knowledgeable, sophisticated and experienced in making investment decisions of this kind and received adequate information about us or had adequate access to information about us. The vendors represented to us that the vendors are not "consultants" for purposes of Nasdaq Listing Rule 5635(c).

Transfer Agent

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The address is 6201 15th Avenue, Brooklyn, NY 11219 and the telephone number is (718) 921-8200.

Holders of Common Stock

As of March 24, 2023, there were 108 holders of record of our common stock. As of such date, 2,924,491 shares of our common stock were issued and outstanding.

Dividends

We have never declared nor paid any cash dividends, and currently intend to retain all our cash and any earnings for use in our business and, therefore, do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our consolidated financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Our Business Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: Specialized BioTherapeutics and Public Health Solutions.

Our Specialized BioTherapeutics business segment is developing and moving toward potential commercialization of HyBryte™ (a proposed proprietary name of SGX301 or synthetic hypericin), a novel photodynamic therapy ("PDT"), utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"). With a successful Phase 3 study completed, regulatory approval is being sought and commercialization activities for this product candidate are being advanced initially in the U.S. Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, our first-in-class innate defense regulator ("IDR") technology, dusquetide (SGX942) for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation including pediatric Crohn's disease (SGX203).

Our Public Health Solutions business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease and our vaccine programs targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases ("NIAID"), the Biomedical Advanced Research and Development Authority ("BARDA") and the Defense Threat Reduction Agency ("DTRA").

An outline of our business strategy follows:

- Following positive primary endpoint results for the Phase 3 FLASH (Florescent Light Activated Synthetic Hypericin) clinical trial of HyBryte™ in CTCL as well as further statistically significant improvement in response rates with longer treatment (18 weeks compared to 12 and 6 weeks of treatment), meet with the United States ("U.S.") Food and Drug Administration ("FDA") to discuss the contents of a refusal to file ("RTF") letter recently issued by the FDA in response to the HyBryte™ new drug application ("NDA") for the treatment of CTCL. We are preparing for a meeting, categorized as Type A, with the FDA to clarify and respond to the issues identified in the RTF letter and to seek additional guidance concerning information that the FDA would require for a resubmitted NDA to be deemed acceptable to file, in order to advance HyBryte™ towards marketing approval and U.S. commercialization while continuing to explore ex-U.S. partnership.

- Expanding development of synthetic hypericin under the research name SGX302 into psoriasis with the conduct of a Phase 2a clinical trial, following the positive Phase 3 FLASH study and positive proof-of-concept demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients.

- Following feedback from the United Kingdom ("UK") Medicines and Healthcare products Regulatory Agency ("MHRA") that a second Phase 3 clinical trial of SGX942 Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE Immunity) would be required to support a marketing authorization; design a second study and attempt to identify a potential partner(s) to continue this development program.

- Continue development of our therapeutic SGX943 and our heat stabilization platform technology, ThermoVax®, in combination with our programs for RiVax® (ricin toxin vaccine), CiVax™ (COVID-19 vaccine) and filovirus vaccines (targeting Ebola, Sudan, and Marburg viruses), with U.S. government funding support.

- Continue to apply for and secure additional government funding for each of our Specialized BioTherapeutics and Public Health Solutions programs through grants, contracts and/or procurements.

- Pursue business development opportunities for our pipeline programs, as well as explore merger/acquisition strategies.

- Acquire or in-license new clinical-stage compounds for development, as well as evaluate new indications with existing pipeline compounds for development.

Corporate Information

We were incorporated in Delaware in 1987 under the name Biological Therapeutics, Inc. In 1987, we merged with Biological Therapeutics, Inc., a North Dakota corporation, pursuant to which we changed our name to "Immunotherapeutics, Inc." We changed our name to "Endorex Corp." in 1996, to "Endorex Corporation" in 1998, to "DOR BioPharma, Inc." in 2001, and finally to "Soligenix, Inc." in 2009. Our principal executive offices are located at 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Our Product Candidates in Development

The following tables summarize our product candidates under development:

Specialized BioTherapeutics Product Candidates*

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
HyBryte™	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate compared to placebo; Phase 3 trial completed; demonstrated statistical significance in primary endpoint in March 2020 (Cycle 1) and demonstrated continued improvement in treatment response with extended treatment in April 2020 (Cycle 2) and

		October 2020 (Cycle 3); NDA filed December 2022; FDA RTF letter received February 2023; Prepare for Type A meeting with the FDA
SGX302	Mild-to-Moderate Psoriasis	Positive proof-of-concept demonstrated in a small Phase 1/2 pilot study; Phase 2a protocol and Investigation New Drug ("IND") clearance received from the FDA; Phase 2a study initiated December 2022
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial completed; demonstrated significant response compared to placebo with positive long-term (12 month) safety also reported; Phase 3 clinical trial results announced December 2020: The primary endpoint of median duration of severe oral mucositis ("SOM") did not achieve the pre-specified criterion for statistical significance ($p \leq 0.05$); although biological activity was observed with a 56% reduction in the median duration of SOM from 18 days in the placebo group to 8 days in the SGX942 treatment group; analyze full dataset from Phase 3 study and design a second Phase 3 clinical trial; continued development contingent upon identification of partnership
SGX203†	Pediatric Crohn's disease	Phase 1/2 clinical trial completed; efficacy data, pharmacokinetic (PK)/pharmacodynamic(PD) profile and safety profile demonstrated; Phase 3 clinical trial initiation contingent upon additional funding, such as through partnership

Public Health Solutions*†

Soligenix Product Candidate	Indication	Stage of Development
ThermoVax®	Thermostability of vaccines for Ricin toxin, Ebola, Sudan, Marburg and SARS- CoV-2 (COVID-19) viruses	Pre-clinical
RiVax®	Vaccine against Ricin Toxin Poisoning	Phase 1a and 1b trials completed, safety and neutralizing antibodies for protection demonstrated; Phase 1c trial initiated December 2019, closed January 2020
SGX943	Therapeutic against Emerging Infectious Diseases	Pre-clinical
CiVax™	Vaccine against COVID-19	Pre-clinical

* *Timelines subject to potential disruption due to COVID-19 outbreak.*

† *Contingent upon continued government contract/grant funding or other funding source.*

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the assumptions and estimates used in the preparation of our financial statements.

Revenue Recognition

Our revenues include revenues generated from government contracts and grants. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fees. These revenues are recognized when expenses have been incurred by subcontractors or when we incur reimbursable internal expenses that are related to the government contracts and grants.

We also record revenue from contracts with customers in accordance with Accounting Standards Codification Topic 606 ("ASC 606"), *Revenue From Contracts with Customers*. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Certain amounts received from or billed to customers in accordance with contract terms are deferred and recognized as future performance obligations are satisfied. All amounts earned under contracts with customers other than sales-based royalties are classified as license revenues. Sales-based royalties under our license agreements would be recognized as royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any royalty revenue.

Research and Development Costs

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contract and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses

as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- contract research organizations ("CROs") in connection with performing research activities on our behalf and conducting preclinical studies and clinical trials on our behalf;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites active and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions such as the fair value of stock options and to accrue for clinical trials in process that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Material Changes in Results of Operations

Year Ended December 31, 2022 Compared to 2021

For the year ended December 31, 2022, we had a net loss of $13,798,339 as compared to a net loss of $12,550,973 for the prior year, representing an increased loss of $1,247,366 or 10%. The increase in net loss is primarily attributed to an increase in legal and consulting expenses associated with the arbitration against Emergent as well as no gain on forgiveness of the loan under the Paycheck Protection Program ("PPP") in 2022. For the year ended December 31, 2022, we had revenues of $948,911 as compared to $824,268 for the prior year, representing an increase of $124,643 or 15%. The increase in revenues was primarily a result of the recognition of licensing revenue in 2022 offset by a decrease in grant revenue.

We incurred costs related to contract and grant revenues in the year ended December 31, 2022 and 2021 of $550,822 and $728,640, respectively, representing a decrease of $177,818 or 24%. The decrease in costs was primarily the result of grants being fully utilized.

Our gross profit for the year ended December 31, 2022 was $398,089 or 42% of total revenues as compared to $95,628 or 12% of total revenues for the prior year, representing an increase of $302,461 or 316%. The increase in gross profit was primarily the result of the recognition of licensing revenue in 2022 as well as a greater percentage of trial work conducted for CiVax™ and SGX943 in 2022 and the higher contract reimbursements associated with those grants.

Research and development expenses decreased by $241,761 or 3% to $7,944,089 for year ended December 31, 2022 as compared to $8,185,850 for the prior year. The decrease in research and development spending for the year ended December 31, 2022 was related to the conclusion of the CTCL and oral mucositis Phase 3 studies in 2021.

General and administrative expenses increased by $1,684,166 or 34%, to $6,692,904 for the year ended December 31, 2022, as compared to $5,008,738 for the prior year. This increase is primarily related to an increase in legal and consulting expenses associated with the arbitration against Emergent.

Other expense for the year ended December 31, 2022 was $714,370 as compared to $316,755 for the prior year, reflecting an increase of $397,615 or 126%. The increase was primarily due to the recognition of gain on forgiveness of the PPP loan in 2021, which reduced the total other expenses in the prior year.

The State of New Jersey's Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused NOL carryforwards to other New Jersey-based corporate taxpayers. We sold 2020 and 2019 New Jersey NOL carryforwards resulting in the recognition of income tax benefits of $1,154,935 and $864,742 during the years ended December 31, 2022 and 2021, respectively. We sold our 2021 New Jersey NOL carryforwards and received $1,161,197, net of transaction costs, in January 2023, which will be recognized in the first quarter of 2023. We have not yet sold our 2022 New Jersey NOL carryforwards but may do so in the future. We will continue to explore opportunities to sell unused NOL carryforwards for the year ended December 31, 2022. However, there can be no assurance as to the continuation or magnitude of this program in future years.

Business Segments

We maintain two active business segments for the years ended December 31, 2022 and 2021: Specialized BioTherapeutics and Public Health Solutions.

The Specialized BioTherapeutics business segment had revenue of $31,929 for the year ended December 31, 2022 as compared to no revenue for the year ended December 31, 2021, representing an increase of $31,929 or 100%. The increase was due to the addition of reimbursable development activity in 2022 under the grant to support the investigator initiated study of HyBryte™ for expanded treatment in patients with early-stage CTCL.

Revenues for the Public Health Solutions business segment for the year ended December 31, 2022 were $916,982 as compared to $824,268 for the year ended December 31, 2021, representing an increase of $92,714 or 11%. The increase in revenues was primarily the result of the recognition of licensing revenue in 2022.

Income from operations for the Public Health Solutions business segment for the year ended December 31, 2022 was $26,612 as compared to a loss of $542,270 for the year ended December 31, 2021, representing an increase $568,882 or 105%. The income for the year ended December 31, 2022 is attributable to the recognition of licensing revenue offset by the additional expenses incurred due to the expiration of grants and contracts. Loss from operations for the Specialized BioTherapeutics business segment for the year ended December 31, 2022 was $7,614,988 as compared to $7,216,450 for the year ended December 31, 2021, representing an increased loss of $398,538 or 6%. This increased loss is primarily attributed to increased expenses associated with preparation for the HyBryte™ NDA filing in 2022.

Financial Condition and Liquidity

Cash and Working Capital

As of December 31, 2022, we had cash and cash equivalents of $13,359,615 as compared to $26,043,897 as of December 31, 2021, representing a decrease of $12,684,282 or 49%. As of December 31, 2022, we had a working capital deficit of $2,663,721, representing a decrease of $22,942,066 as compared to working capital of $20,278,345 for the prior year. The decrease in cash and cash equivalents and working capital was primarily related to cash used in operating activities. The decrease in working capital is also due to the impact of the entire convertible debt balance being classified as a current liability as of December 31, 2022 due to a subjective acceleration clause included in the debt agreement and a potential breach of a cash debt covenant during the twelve month look-forward period from the filing of our financial statements.

We believe that we have sufficient resources available to support our development activities and business operations and timely satisfy our obligations as they become due into the third quarter of 2023. We do not have sufficient cash and cash equivalents as of the date of filing this Annual Report on Form 10-K to support our operations for at least the 12 months following the date the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern through 12 months after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to secure additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations, securing additional proceeds from government contract and grant programs, securing additional proceeds available from the sale of shares of our common stock via the At Market Issuance Sales Agreement ("B. Riley Sales Agreement") with B. Riley Securities, Inc. ("B. Riley") and potentially amending the loan agreement with Pontifax to reduce the conversion price in order to allow for conversion of a portion of the debt which will reduce our debt repayments; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, identify and enter into any strategic transactions that will provide the capital that we will require or achieve the other strategies to alleviate the conditions that raise substantial doubt about our ability to continue as a going concern. If none of these alternatives are available, or if available, are not available on satisfactory terms, we will not have sufficient cash resources and liquidity to fund our business operations for at least the 12 months following the date the financial statements are issued. The failure to obtain sufficient capital on acceptable terms when needed may require us to delay, limit, or eliminate the development of business opportunities and our ability to achieve our business objectives and our competitiveness, and our business, financial condition, and results of operations will be materially adversely affected. In addition, market instability, including as a result of geopolitical instability, may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. In addition, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Our plans with respect to our liquidity management include, but are not limited to, the following:

- We have up to $1.7 million in active government grant funding still available as of December 31, 2022 to support our associated research programs through May 2026, provided the federal agencies do not elect to terminate the grants for convenience. We plan to submit additional contract and grant applications for further support of our programs with various funding agencies. However, there can be no assurance that we will obtain additional governmental grant funding;

- We have continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expect to continue to do so for the foreseeable future;

- We will continue to pursue NOL sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program if the program is available;

- We plan to pursue potential partnerships for pipeline programs as well as continue to explore merger and acquisition strategies. However, there can be no assurances that we can consummate such transactions;

- We have up to $26.6 million remaining from the B. Riley Sales Agreement as of March 24, 2023 under the prospectus supplement updated August 13, 2021, subject to the limitations imposed by General Instruction I.B.6 to Form S-3; and

- We may seek additional capital in the private and/or public equity markets, pursue government contracts and grants as well as business development activities, to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity/debt financing opportunities on an ongoing basis and may execute them when appropriate. However, there

can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

Reverse Stock Split

On February 9, 2023, we completed a reverse stock split of our issued and outstanding shares of common stock at a ratio of one-for-fifteen, whereby, every fifteen shares of our issued and outstanding common stock was converted automatically into one issued and outstanding share of common stock without any change in the par value per share. No fractional shares were issued as a result of the reverse stock split. Any fractional shares that would otherwise have resulted from the reverse stock split were rounded up to the next whole number. Our common stock began trading on The NASDAQ Capital Market on a reverse split basis at the market opening on February 10, 2023. All share and per share data have been restated to reflect this reverse stock split.

Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the year ending December 31, 2023 to be approximately $3.7 million before any contract or grant reimbursements, of which $3.2 million relates to the Specialized BioTherapeutics business and $0.5 million relates to the Public Health Solutions business. We anticipate contract and grant reimbursements for the same period of approximately $0.7 million to offset research and development expenses in the Specialized BioTherapeutics and Public Health Solutions business segments.

The table below details our costs for research and development by program and amounts reimbursed for the years ended December 31, 2022 and 2021:

	2022	2021
Research & Development Expenses		
RiVax® and ThermoVax® Vaccines	**$ 346,894**	$ 616,598
SGX942 (Dusquetide)	**295,376**	2,284,731
CiVax™	**22,901**	20,000
HyBryte™ (SGX301 or synthetic hypericin)	**6,831,827**	4,720,377
Other	**447,091**	544,144
Total	**$ 7,944,089**	$ 8,185,850
Reimbursed under Government Contracts and Grants		
RiVax® and ThermoVax® Vaccines	**$ 22,161**	$ 146,913
CiVax™	**398,001**	514,436
SGX943	**98,731**	67,291
HyBryte™ (investigator initiated study)	**31,929**	—
Total	**550,822**	728,640
Grand Total	**$ 8,494,911**	$ 8,914,490

Contractual Obligations

We have licensing fee commitments of approximately $230,000 as of December 31, 2022 over the next five years for several licensing agreements with partners and universities. Additionally, we have collaboration and license agreements, which upon clinical or commercialization success may require the payment of milestones of up to approximately $13.2 million, royalties on net sales of covered products ranging from 2% to 3%, sub-license IND milestones on covered products of up to approximately $200,000, sub-license income royalties on covered products up to 15% and sub-license global net sales royalties on covered products ranging from 1.5% to 2.5%, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

We currently lease approximately 6,200 square feet of office space at 29 Emmons Drive, Suite B-10 in Princeton, New Jersey. This office space currently serves as our corporate headquarters, and both of our business segments (Specialized BioTherapeutics and Public Health Solutions), operate from this space. Pursuant to an amendment on June 21, 2022, the lease has been extended from November 2022 to October 2025. The current rent is approximately $11,108 per month and

will remain so through October 2023. The rent for lease periods starting November 2023 and November 2024 is approximately $11,367 per month and $11,625 per month, respectively. Our office space is sufficient for our current needs.

In September 2014, we entered into an asset purchase agreement with Hy Biopharma pursuant to which we acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma's synthetic hypericin product. As consideration for the assets acquired, we initially paid $275,000 in cash and issued 12,328 shares of common stock with a fair value based upon our stock price on the date of grant of $3.75 million. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in our research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the U.S.

In January 2020, our Board of Directors authorized an amendment to Dr. Schaber's employment agreement to increase the number of shares of common stock from 334 to 33,334, issuable to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party.

In March 2020, we filed a prospectus supplement covering the offer and sale of up to 130,413 shares of our common stock, which were issued to Hy Biopharma. We were required to issue the shares to Hy Biopharma as payment following the achievement of a milestone under the asset purchase agreement, specifically, the Phase 3 clinical trial of HyBryte™ being successful in the treatment of CTCL. The number of shares of our common stock issued to Hy Biopharma was calculated using an effective price of $38.40 per share, based upon a formula set forth in the asset purchase agreement.

Provided the final success-oriented milestone is attained, we will be required to make a payment of up to $5.0 million, if and when achieved. The potential future payment will be payable in our common stock, not to exceed 19.9% of our outstanding stock.

In December 2020, we entered into a $20 million convertible debt financing agreement with Pontifax Medison Finance ("Pontifax"), the healthcare-dedicated venture and debt fund of the Pontifax life science funds. Under the terms of the agreement with Pontifax, we had access to up to $20 million in convertible debt financing in three tranches, which will mature on June 15, 2025 and had an interest only period through December 2022 with a rate of 8.47% on borrowed amounts and a 1% rate on amounts available but not borrowed. Upon the closing of this transaction, we borrowed the first tranche of $10 million. We did not utilize our option to draw the second or third tranche of $5 million each, which expired on December 15, 2021 and March 15, 2022, respectively. Interest expense incurred and paid in 2022 totaled $847,000 and $857,411, respectively.

Pontifax may elect to convert the outstanding loan drawn under the first tranche into shares of our common stock at any time prior to repayment at a conversion price of $61.50 per share. We also have the ability to force the conversion of the loan into shares of our common stock, subject to certain conditions.

CARES Act Loan

On April 13, 2020, we were advised that one of our principal banks, JPMorgan Chase Bank, N.A., had approved a $417,830 loan (the "Loan") under the PPP pursuant to the Coronavirus Aid, Relief and Economic Security Act that was signed into law on March 27, 2020.

As a U.S. small business, we qualified for the PPP, which allows businesses and nonprofits with fewer than 500 employees to obtain loans of up to $10 million to incentivize companies to maintain their workers as they manage the business disruptions caused by the COVID-19 pandemic. The PPP provides for loans for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The PPP loan proceeds may be used for eligible purposes, including payroll, benefits, rent and utilities.

The Loan had a term of two years, was unsecured, and was guaranteed by the Small Business Administration ("SBA"). The Loan bore interest at a fixed rate of 0.98% per annum, with interest and principal deferred during the eight-week or twenty-four-week period following the Loan origination date ("the loan forgiveness period") and subsequent 10 months. Some or all of the Loan was eligible for forgiveness if at least 60% of the Loan proceeds were used by us to cover payroll costs, including benefits and if we maintained our employment and compensation within certain parameters during the loan

forgiveness period and complied with other relevant conditions. We used the proceeds for purposes consistent with the PPP and met the conditions for forgiveness of the Loan.

On June 29, 2021, the SBA and JPMorgan notified us that the entire balance of this note has been forgiven. We recorded the forgiveness of the principal and accrued interest of $421,584 as a gain on forgiveness in other income on the consolidated statement of operations for the year ended December 31, 2021.

Contingencies

We follow subtopic 450-20 of the FASB Accounting Standards Codification to report accounting for contingencies. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to us but which will only be resolved when one or more future events occur or fail to occur. We assess such contingent liabilities, and such assessment inherently involves an exercise of judgment. A liability is only recorded if management determines that it is both probable and reasonably estimable.

COVID-19

Based on the current outbreak of SARS-CoV-2, the pathogen responsible for COVID-19, which has already had an impact on financial markets, there could be additional repercussions to our operating business, including but not limited to, the sourcing of materials for product candidates, manufacture of supplies for preclinical and/or clinical studies, delays in clinical operations, which may include the availability or the continued availability of patients for trials due to such things as quarantines, conduct of patient monitoring and clinical trial data retrieval at investigational study sites.

COVID-19 affected our operations but did not have a material impact on our business, operating results, financial condition or cash flows as of and for the year ended December 31, 2022. In particular, due to delays by our third party commercial active pharmaceutical ingredient contract manufacturer of HyBryte™ we were unable to provide the pre-requisite amount of accrued stability data required to file the HyBryte™ NDA with the FDA by the first half of 2022. Therefore, we filed the NDA with the FDA in December of 2022.

The future impact of the outbreak is highly uncertain and cannot be predicted, and we cannot provide any assurance that the outbreak will not have a material adverse impact on our operations or future results or filings with regulatory health authorities. The extent of the impact to us, if any, will depend on future developments, including actions taken to contain the coronavirus.

Emergent BioSolutions Legal Proceedings

In July 2020, we filed a demand for arbitration against Emergent BioSolutions, Inc. and certain of its subsidiaries (collectively, “Emergent”) with the American Arbitration Association in Mercer County, New Jersey. We allege in the arbitration various breaches of contracts and warranties as well as acts of fraud. Emergent has answered that demand for arbitration denying the allegations and asserting affirmative defenses. We presented our case at an arbitration hearing over 12 days in January 2022. Following submission of post-hearing briefs, the arbitration panel heard closing oral arguments in April 2022. We sought to recover damages in excess of $19 million from Emergent.

On July 6, 2022, the American Arbitration Association entered a final decision in connection with this arbitration. Despite the arbitration panel ruling that Emergent had committed a number of breaches of the parties’ contracts, the panel did not award monetary damages to us. On September 30, 2022, we filed a petition to vacate the arbitration decision with the Delaware Court of Chancery, requesting that the Court vacate the arbitration decision and remand the matter to the arbitration panel for rehearing. We cannot offer any assurances as to any result of our challenge of the arbitration decision or that we will recover any damages from Emergent (see Part I, Item 3 – Legal Proceedings).

We have received invoices from Emergent related to the above matter. No accrual has been made for these invoices as management deems them invalid and not probable of being required to pay them based on the numerous breaches cited in the arbitration. These invoices total approximately $331,000.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-22 of this Annual Report on Form 10-K and is incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the possible controls and procedures.

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, our management, including our principal executive officer and principal financial officer, has concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Company management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework, 2013*.

Based on our assessment, management has concluded that, as of December 31, 2022, our internal control over financial reporting is effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

We have not experienced any material impact to our internal controls over financial reporting despite the fact that our employees are working on a hybrid schedule both in-office and remotely since returning from the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact of their design and operating effectiveness.

Item 9B. Other Information

Item 9C Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The table below contains information regarding the current members of the Board of Directors and executive officers. The ages of individuals are provided as of March 24, 2023.

Name	Age	Position
Christopher J. Schaber, PhD	56	Chairman of the Board, Chief Executive Officer and President
Gregg A. Lapointe, CPA, MBA	64	Director
Diane L Parks, MBA	70	Director
Robert J. Rubin, MD	77	Director
Jerome B. Zeldis, MD, PhD	72	Director
Jonathan Guarino, CPA, CGMA	50	Chief Financial Officer, Senior Vice President and Corporate Secretary
Oreola Donini, PhD	51	Chief Scientific Officer and Senior Vice President
Richard Straube, MD	71	Chief Medical Officer and Senior Vice President

Christopher J. Schaber, PhD has over 33 years of experience in the pharmaceutical and biotechnology industry. Dr. Schaber has been our President and Chief Executive Officer and a director since August 2006. He was appointed Chairman of the Board in October 2009. He also has served on the board of directors of the Biotechnology Council of New Jersey ("BioNJ") since January 2009 and the Alliance for Biosecurity since October 2014, and has been a member of the corporate council of the National Organization for Rare Disorders ("NORD") since October 2009. He also serves on the scientific advisory board for private start-up medical device company, Simphotek, Inc. Prior to joining Soligenix, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, pre-clinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his BA degree from Western Maryland College, his MS degree in Pharmaceutics from Temple University School of Pharmacy and his PhD degree in Pharmaceutical Sciences from the Union Graduate School. During his career, Dr. Schaber has played a significant role in raising in excess of $350 million through both public offerings and private placements, as well as approximately $100 million in non-dilutive funding awards from state and federal governmental agencies. Dr. Schaber was selected to serve as a member of our Board of Directors because of his extensive experience in drug development and pharmaceutical operations, including his experience as a senior executive officer with our Company and Discovery Laboratories, Inc., and as a member

of the board of directors of BioNJ and Simphotek; because of his proven ability to raise funds and provide access to capital; and because of his advanced degrees in science and business.

Gregg A. Lapointe, CPA, MBA has been a director since March 2009. Mr. Lapointe is currently CEO of Cerium Pharmaceuticals, Inc. and serves on the board of directors of Rigel Pharmaceuticals, Inc., and Astria Therapeutics, Inc. as other private biopharma companies. Mr. Lapointe has previously served on the board of directors of ImmunoCellular Therapeutics Ltd., Raptor Pharmaceuticals, Inc., SciClone Pharmaceuticals, Inc., the Pharmaceuticals Research and Manufacturers of America (PhRMA), Questcor Pharmaceuticals, Inc. and the board of trustees of the Keck Graduate Institute of Applied Life Sciences. He previously served in varying roles for Sigma-Tau Pharmaceuticals, Inc. (now known as Leadiant Biosciences, Inc.), a private biopharmaceutical company, from September 2001 through February 2012, including Chief Operating Officer from November 2003 to April 2008 and Chief Executive Officer from April 2008 to February 2012. From May, 1996 to August 2001, he served as Vice President of Operations and Vice President, Controller of AstenJohnson, Inc. (formerly JWI Inc.). Prior to that, Mr. Lapointe spent several years in the Canadian medical products industry in both distribution and manufacturing. Mr. Lapointe began his career at Price Waterhouse. Mr. Lapointe received his B.A. degree in Commerce from Concordia University in Montreal, Canada, a graduate diploma in Accountancy from McGill University and his M.B.A. degree from Duke University. He is a C.P.A. in the state of Illinois. Mr. Lapointe was selected to serve as a member of our Board of Directors because of his significant experience in the areas of global strategic planning and implementation, business development, corporate finance, and acquisitions, and his experience as an executive officer and board member in the pharmaceutical and medical products industries.

Diane L. Parks, MBA has been a director since July 2019. From February 2016 until July 2018, she served as Head of U.S. Commercial and Senior Vice President of Marketing, Sales & Market Research at Kite Pharma, Inc., a biopharma company developing cancer immunotherapy products with a primary focus on genetically engineered autologous T cell therapy with chimeric antigen receptors. From October 2014 to October 2015, Ms. Parks served as Vice President of Global Marketing at Pharmacyclics LLC, a biopharmaceutical company primarily focused on the development of cancer therapies. Prior to Pharmacyclics LLC, Ms. Parks held senior leadership roles as Vice President of Sales for Amgen, Inc., a biopharmaceutical company, representing oncology and nephrology products, and Senior Vice President of Specialty Biotherapeutics and Managed Care at Genentech, Inc., a biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions that was acquired by Roche Holding AG in 2009. At Genentech, she led the launches of multiple products as well as commercial development of Lucentis® and Rituxan®. Since 2019, she has been a member of the board of directors of several biopharmaceutical companies trading on the Nasdaq including Calliditas Therapeutics AB, Kura Oncology, Inc., CTI BioPharma and Celularity. She also serves on the board of directors for TriSalus Life Sciences, a private biopharmaceutical company. Since September 2020, Ms. Parks has been a member of the board of directors for a non-profit company called Lymphoma Research Foundation, which is devoted exclusively to funding lymphoma research and serving those impacted by blood cancer. Ms. Parks holds a BS from Kansas State University and an MBA in marketing from Georgia State University. She has been a commercial leader in the biotech and pharma industry for over 30 years. Ms. Parks was selected to serve as a member of our Board of Directors because of her over 30 years' experience as a businesswoman and commercial executive with an extensive record of driving profitable growth for large pharmaceutical and biotech companies.

Robert J. Rubin, MD has been a director since October 2009. Dr. Rubin was a clinical professor of medicine at Georgetown University from 1995 until 2012 when he was appointed a Distinguished Professor of Medicine. From 1987 to 2001, he was President of the Lewin Group (purchased by Quintiles Transnational Corp. in 1996), an international health policy and management consulting firm. From 1994 to 1996, Dr. Rubin served as Medical Director of ValueRx, a pharmaceutical benefits company. From 1992 to 1996, Dr. Rubin served as President of Lewin-VHI, a health care consulting company. From 1987 to 1992, he served as President of Lewin-ICF, a health care consulting company. From 1984 to 1987, Dr. Rubin served as a principal of ICF, Inc., a health care consulting company. From 1981 to 1984, Dr. Rubin served as the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services and as an Assistant Surgeon General in the U.S. Public Health Service. Dr. Rubin currently serves on the Board of Cerium Pharmaceuticals where he is also the acting Chief Medical Officer since July 2022. Dr. Rubin has served on the Board of BioTelemetry, Inc. (formerly known as CardioNet, Inc.) from 2007 to February 2021. He is a board certified nephrologist and internist. Dr. Rubin received an undergraduate degree in Political Science from Williams College and his medical degree from Cornell University Medical College. Dr. Rubin was selected to serve as a member of our Board of Directors because of his vast experience in the health care industry, including his experience as a nephrologist, internist, clinical professor of medicine and Assistant Surgeon General, and his business experience in the pharmaceutical industry.

Jerome B. Zeldis, MD, PhD has been a director since June 2011. Dr. Zeldis is currently Chief Medical Officer and President of Clinical Research, Drug Safety and Regulatory of Sorrento Therapeutics, Inc. He is also Chief Medical Officer and Principal at Celularity, Inc. Previously, Dr. Zeldis was Chief Executive Officer of Celgene Global Health and Chief Medical Officer of Celgene Corporation, a publicly traded, fully integrated biopharmaceutical company. He was employed by Celgene Corporation from 1997 to 2016. From September 1994 to February 1997, Dr. Zeldis worked at Sandoz Research Institute and the Janssen Research Institute in both clinical research and medical development. He has been a board member of several biotechnology companies and is currently on the boards of Metastat, Inc., PTC Therapeutics Inc., BioSig Technologies, Inc., the Castleman's Disease Organization and Alliqua, Inc. He has previously served on the boards of the NJ Chapter of the Arthritis Foundation and PTC Therapeutics, Inc. Additionally, he has served as Assistant Professor of Medicine at the Harvard Medical School (from July 1987 to September 1988), Associate Professor of Medicine at University of California, Davis from (September 1988 to September 1994), Clinical Associate Professor of Medicine at Cornell Medical School (January 1995 to December 2003) and Professor of Clinical Medicine at the Robert Wood Johnson Medical School (July 1998 to June 2010). Dr. Zeldis received a BA and an MS from Brown University, and an MD, and a PhD in Molecular Biophysics and Biochemistry from Yale University. Dr. Zeldis trained in Internal Medicine at the UCLA Center for the Health Sciences and in Gastroenterology at the Massachusetts General Hospital and Harvard Medical School. Dr. Zeldis was selected to serve as a member of our Board of Directors because of his experience as an executive officer of a publicly traded biopharmaceutical company and in clinical research and medical development, and his experience in the health care industry, including his experience as an internist, gastroenterologist and professor of medicine.

Jonathan Guarino, CPA, CGMA has been with our company since September 2019 and is currently our Senior Vice President and Chief Financial Officer. Mr. Guarino has had significant experience with both development-stage and commercial companies. From September 2016 to July 2019, he served as Corporate Controller for Hepion Pharmaceuticals, Inc. (formerly ContraVir Pharmaceuticals, Inc.), a New Jersey-based public biotechnology company, where he contributed to the establishment of the financial infrastructure, as well as assisted with capital fund-raising and debt financings. He worked as Controller for Suite K Value Added Services LLC from August 2015 to September 2016 and as a senior manager of technical accounting for Covance, Inc., from June 2014 to May 2015. Prior to these positions, he held accounting and finance positions of increasing importance with several companies, including PricewaterhouseCoopers LLP, BlackRock, Inc. and Barnes & Noble, Inc. Mr. Guarino is a CPA (certified public accountant) and CGMA (chartered global management accountant), who received his BS in Business from Montclair State University.

Oreola Donini, PhD, has been with our company since August 2013 and is currently our Senior Vice President and Chief Scientific Officer, a position she has held since December 2014. Dr. Donini served as our Vice President of Preclinical Research and Development from August 2013 until December 2014. She has more than 20 years' experience in drug discovery and preclinical development with start-up biotechnology companies. From 2012 to 2013, Dr. Donini worked with ESSA Pharma Inc. as Vice President Research and Development. From 2004 to 2013, Dr. Donini worked with Inimex Pharmaceuticals Inc. ("Inimex"), lastly as Senior Director of Preclinical R&D from 2007 to 2013. Prior to joining Inimex, she worked with Kinetek Pharmaceuticals Inc., developing therapies for infectious disease, cancer and cancer supportive care. Dr. Donini is a co-inventor and leader of our SGX94 innate defense regulator technology, developed by Inimex and subsequently acquired by us. She was responsible for overseeing the manufacturing and preclinical testing of SGX94, which demonstrated efficacy in combating bacterial infections and mitigating the effects of tissue damage due to trauma, infection, radiation and/or chemotherapy treatment. These preclinical studies resulted in a successful Phase 1 clinical study and clearance of Phase 2 protocols for oral mucositis in head and neck cancer and acute bacterial skin and skin structure infections. While with ESSA Pharma Inc. as the Vice President of Research and Development, Dr. Donini led the preclinical testing of a novel N-terminal domain inhibitor of the androgen receptor for the treatment of prostate cancer. While with Kinetek Pharmaceuticals Inc., her work related to the discovery of novel kinase and phosphatase inhibitors for the treatment of cancer. Dr. Donini received her PhD from Queen's University in Kinston, Ontario, Canada and completed her post-doctoral work at the University of California, San Francisco. Her research has spanned drug discovery, preclinical development, manufacturing and clinical development in infectious disease, cancer and cancer supportive care.

Richard Straube, MD has been with our company since January 2014 and is currently our Senior Vice President and Chief Medical Officer. Dr. Straube is a board-certified pediatrician with 36 years' experience in both academia and industry, including clinical research experience in host-response modulation. From 2009 until joining our company, he was Chief Medical Officer of Stealth Peptides Incorporated, a privately-held, clinical stage, biopharmaceutical company. Prior to joining us, Dr. Straube served from 1988 to 1993 in various capacities, including most recently as Senior Director, Infectious Diseases and Immunology, Clinical Research, for Centocor, Inc., a privately-held biopharmaceutical company focused on developing monoclonal antibody-based diagnostics. While at Centocor, Inc., Dr. Straube was responsible for the initial anti-cytokine and anti-endotoxin programs targeted at ameliorating inappropriate host responses to infectious and immunologic

challenges. Programs that he managed at Centocor, Inc. include assessments of immunomodulation using monoclonal removal of inciting molecular triggers, removal of internal immune-messengers, augmentation of normal host defenses, and maintenance of normal sub-cellular function in the face of injury. From 1993 to 1995, Dr. Straube was Director of Medical Affairs at T-cell Sciences, Inc., a privately-held biotechnology company. From 1995 to 1997, he was Director of Clinical Investigations of the Pharmaceutical Products Division of Ohmeda Corp., a privately-held biopharmaceutical company. He served from 1998 to 2007 as Executive Vice President of Research and Development and Chief Scientific Officer at INO Therapeutics LLC, a privately-held biotherapeutics company, where he was responsible for the clinical trials and subsequent approval of inhaled nitric oxide for the treatment of persistent pulmonary hypertension of the newborn. From 2007 to 2009, Dr. Straube was the Chief Medical Officer at Critical Biologics Corporation, a privately-held biotechnology company. Dr. Straube received his medical degree and residency training at the University of Chicago, completed a joint adult and pediatrician infectious diseases fellowship at the University of California, San Diego ("UCSD"), and as a Milbank Scholar completed training in clinical trial design at the London School of Hygiene and Tropical Medicine. While on the faculty at the UCSD Medical Center, his research focused on interventional studies for serious viral infections.

Board Leadership Structure

Our Board of Directors believes that Dr. Schaber's service as both the Chairman of our Board of Directors and our Chief Executive Officer is in the best interest of our Company and our stockholders. Dr. Schaber possesses detailed and in-depth knowledge of the issues, opportunities and challenges facing our Company and our business and, therefore, is best positioned to develop agendas that ensure that the Board of Directors' time and attention are focused on the most important matters. His combined role enables decisive leadership, ensures clear accountability, and enhances our ability to communicate our message and strategy clearly and consistently to our stockholders, employees, and collaborative partners.

Mr. Lapointe, Ms. Parks, Dr. Rubin, and Dr. Zeldis are independent and the Board of Directors believes that the independent directors provide effective oversight of management. Moreover, in addition to feedback provided during the course of meetings of the Board of Directors, the independent directors hold executive sessions. Following an executive session of independent directors, the independent directors' report back to the full Board of Directors regarding any specific feedback or issues, provide the Chairman with input regarding agenda items for Board of Directors and Committee meetings, and coordinate with the Chairman regarding information to be provided to the independent directors in performing their duties. The Board of Directors believes that this approach appropriately and effectively complements the combined Chairman/Chief Executive Officer structure.

Although we believe that the combination of the Chairman and Chief Executive Officer roles is appropriate under the current circumstances, our corporate governance guidelines do not establish this approach as a policy, and the Board of Directors may determine that it is more appropriate to separate the roles in the future.

Committees of the Board of Directors

Our Board of Directors has the following three committees: (1) Compensation, (2) Audit and (3) Nominating and Corporate Governance. Our Board of Directors has adopted a written charter for each of these committees, which are available on our website at www.soligenix.com under the "Investors" section.

Director	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee
Gregg A. Lapointe, CPA	C		M
Diane L. Parks, MBA	M	M	
Robert J. Rubin, MD	M	C	M
Jerome B. Zeldis, MD, PhD		M	C

C – Committee Chair

M – Member

Audit Committee

Our Board of Directors has an Audit Committee, which is comprised of Mr. Lapointe (Chair), Ms. Parks and Dr. Rubin. The Audit Committee assists our Board of Directors in monitoring the financial reporting process, the internal control structure and the independent registered public accountants. Its primary duties are to serve as an independent and objective party to monitor the financial reporting process and internal control system, to review and appraise the audit effort of the independent registered public accountants and to provide an open avenue of communication among the independent registered public accountants, financial and senior management, and our Board of Directors. Our Board of Directors has determined that Mr. Lapointe, Ms. Parks and Dr. Rubin are "independent" directors, within the meaning of applicable listing standards of The Nasdaq Stock Market LLC ("Nasdaq") and the Exchange Act and the rules and regulations thereunder. Our Board of Directors has also determined that the members of the Audit Committee are qualified to serve on the committee and have the experience and knowledge to perform the duties required of the committee and that Mr. Lapointe qualifies as an "audit committee financial expert" as that term is defined in the applicable regulations of the Exchange Act.

Compensation Committee

Our Board of Directors has a Compensation Committee, which is comprised of Dr. Rubin (Chair), Ms. Parks and Dr. Zeldis. The Compensation Committee is responsible for reviewing and approving the executive compensation program, assessing executive performance, setting salary, making grants of annual incentive compensation and approving certain employment agreements. Our Board of Directors has determined that Dr. Rubin, Mr. Lapointe and Dr. Zeldis are "independent" directors within the meaning of applicable listing standards of Nasdaq and the Exchange Act and the rules and regulations thereunder.

Nominating and Corporate Governance Committee

Our Board of Directors has a Nominating and Corporate Governance Committee ("Nominating Committee"), which is comprised of Dr. Zeldis (Chair), Mr. Lapointe and Dr. Rubin. The Nominating Committee makes recommendations to the Board of Directors regarding the size and composition of our Board of Directors, establishes procedures for the nomination process, identifies and recommends candidates for election to our Board of Directors. Our Board of Directors has determined that Dr. Zeldis, Mr. Lapointe and Ms. Parks are "independent" directors, as such term is defined by the applicable Nasdaq listing standards.

Code of Ethics

We have adopted a code of ethics that applies to all our executive officers and senior financial officers (including our chief executive officer, chief financial officer, chief accounting officer and any person performing similar functions). A copy of our code of ethics is publicly available on our website at www.soligenix.com under the "Investors" section. If we make any substantive amendments to our code of ethics or grant any waiver, including any implicit waiver, from a provision of the code to our chief executive officer, chief financial officer or chief accounting officer, we will disclose the nature of such amendment or waiver in a Current Report on Form 8-K.

Diversity Considerations in Identifying Director Nominees

We do not have a formal diversity policy or set of guidelines in selecting and appointing directors that comprise our Board of Directors. However, when making recommendations to our Board of Directors regarding the size and composition of our Board of Directors, our Nominating Committee does consider each individual director's qualifications, skills, business experience and capacity to serve as a director and the diversity of these attributes for the Board of Directors as a whole.

Compensation Committee Interlocks and Insider Participation

No member of our Compensation Committee is or has at any time during the past year been one of our officers or employees. None of our executive officers currently serves or in the past year has served as a member of the Board of Directors or Compensation Committee of any entity that has one or more executive officers serving on our Board of Directors or Compensation Committee.

Item 11. Executive Compensation

In 2018, in furtherance of our compensation philosophy and objectives, the Compensation Committee engaged Setren Smallberg & Associates ("SS&A"), an outside executive compensation consulting firm determined to be independent by the Compensation Committee, to conduct a review of, and recommend changes to, our compensation program for our most highly compensated executive officers. A representative of SS&A attended Compensation Committee meetings at the invitation of the Compensation Committee Chairman and was also in direct contact with the Compensation Committee and company management from time to time. SS&A provided the Compensation Committee with assistance and advice in the review of our salary structure, annual and equity incentive awards and other related executive pay issues. In addition, SS&A provided advice regarding marketplace trends and best practices relating to competitive pay levels.

SS&A did not provide any services to us other than its services as the Compensation Committee's independent compensation consultant, and SS&A did not receive any fees or compensation from us other than the fee it received as the independent compensation consultant. SS&A did not provide any services to us in 2021 or 2022. The Compensation Committee confirmed that SS&A's work for the Compensation Committee did not create any conflicts of interest.

Summary Compensation

The following table contains information concerning the compensation paid during each of the two years ended December 31, 2022 and 2021, respectively to our Chief Executive Officer and each of the three other most highly compensated executive officers (collectively, the "Named Executive Officers").

Summary Compensation

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber [1]	CEO &	2022	$ 499,496	$ 107,891	$ 73,059	$ 30,740	$ 711,185
	President	2021	$ 484,948	$ 96,990	$ 75,951	$ 29,520	$ 687,409
Jonathan Guarino [2]	CFO &	2022	$ 231,132	$ 42,436	$ 51,042	$ 30,740	$ 355,350
	Senior VP	2021	$ 224,400	$ 38,372	$ 3,893	$ 29,520	$ 296,185
Oreola Donini [3]	CSO &	2022	$ 280,800	$ 51,555	$ 27,259	$ 4,628	$ 364,242
	Senior VP	2021	$ 260,000	$ 53,000	$ 33,296	$ 4,783	$ 351,079
Richard C. Straube [4]	CMO &	2022	$ 182,174	$ 32,901	$ 27,259	$ —	$ 242,334
	Senior VP	2021	$ 176,868	$ 29,183	$ 19,027	$ —	$ 225,078

(1) Dr. Schaber deferred the payment of his 2022 bonus of $107,891 until January 15, 2023. Option awards figure includes the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us.

(2) Mr. Guarino deferred the payment of his 2022 bonus of $42,436 until January 15, 2023. Option awards figure includes the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us.

(3) Dr. Donini deferred the payment of her 2022 bonus of $51,555 until January 15, 2023. Option awards figure includes the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us.

(4) Dr. Straube deferred the payment of his 2022 bonus of $32,901 until January 15, 2023. Option awards figure includes the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us.

Employment and Severance Agreements

In August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, PhD. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of $300,000 per year and a minimum annual bonus of $100,000. Dr. Schaber's employment agreement automatically renews every three years, unless otherwise terminated, and last was automatically renewed in December 2019 for an additional term of three years. We agreed to issue him options to purchase 833 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Schaber nine months of severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Schaber and his dependents. No unvested options shall vest beyond the termination date. Dr. Schaber's monetary compensation (base salary of $300,000 and bonus of $100,000) remained unchanged from 2006 with the 2007 renewal. Upon a change in control of the company due to merger or acquisition, all of Dr. Schaber's options shall become fully vested, and be exercisable for a period of five years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during the term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Schaber's immediate family.

In January 2020, our Board of Directors authorized an amendment to Dr. Schaber's employment agreement to increase the number of shares of common stock from 334 to 33,334, issuable to Dr. Schaber immediately prior to the completion of a transaction or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party.

In December 2020, our Board of Directors authorized an amendment to Dr. Schaber's employment agreement to modify the severance terms. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Schaber twelve months of severance, as well as a pro rata bonus calculated by the average of his prior two year's annual bonuses, if any, and based on the number of months that he was employed during the year in which his employment was terminated; however, in the case of termination without "Just Cause" within one year following a change in control or the sale or other disposition of all or substantially all of our assets Dr. Schaber will be entitled 18 months of severance and health insurance and life insurance benefits for him and his dependents.

On June 22, 2011, the Compensation Committee eliminated his fixed minimum annual bonus payable and revised it to an annual targeted bonus of 40% of his annual base salary. On December 10, 2020, the Compensation Committee approved an increase in salary for Dr. Schaber to $484,948. On December 10, 2021, the Compensation Committee approved an increase in salary for Dr. Schaber to $499,496. On December 8, 2022, the Compensation Committee approved an increase in salary for Dr. Schaber to $519,476.

In July 2013, we entered into a one-year employment agreement with Oreola Donini, PhD, our Vice President Preclinical Research & Development. Pursuant to the agreement, we agreed to pay Dr. Donini $170,000 (CAD) per year and a targeted annual bonus of 20% of base salary. We also issued her options to purchase 2,666 shares of our common stock with one-quarter immediately vesting and the remainder vesting over three years. Dr. Donini's employment agreement automatically renews each year, unless otherwise terminated, and has automatically renewed each year since execution. Upon termination without "Just Cause", as defined in Dr. Donini's employment agreement, we would pay Dr. Donini three months of severance, accrued bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. In December 2014, Dr. Donini was named Chief Scientific Officer and Senior Vice President. Upon Dr. Donini's promotion to Chief Scientific Officer, the Compensation Committee increased her targeted bonus to 30% of her annual base salary. On December 10, 2020, the Compensation Committee approved an increase in salary for Dr. Donini to $260,000. On December 10, 2021, the Compensation Committee approved an increase in salary for Dr. Donini to $280,800. On December 8, 2022, the Compensation Committee approved an increase in salary for Dr. Donini to $300,000.

In December 2014, we entered into a one-year employment agreement with Richard C. Straube, MD, our Chief Medical Officer and Senior Vice President. Pursuant to the agreement, we agreed to pay Dr. Straube $300,000 per year and a targeted annual bonus of 30% of base salary. We also issued him options to purchase 666 shares of our common stock with one-third immediately vesting and the remainder vesting over three years. On March 26, 2019, we entered into an amendment to our employment agreement with Dr. Straube. Pursuant to the amended agreement, which amendment becomes effective as of April 1, 2019, Dr. Straube will be required to devote at least 20 hours per week to the performance of his duties and we will pay him $170,000 per year. The amended employment agreement automatically renews each year, unless otherwise terminated. Upon termination without "Just Cause", as defined in the amended employment agreement,

we would pay Dr. Straube one month of severance. No unvested options vest beyond the termination date. On December 10, 2020, the Compensation Committee approved an increase in salary for Dr. Straube to $176,868. On December 10, 2021, the Compensation Committee approved an increase in salary for Dr. Straube to $182,174. On December 8, 2022, the Compensation Committee approved an increase in salary for Dr. Straube to $189,461.

On September 9, 2019, we entered into a one-year employment agreement with Jonathan Guarino, CPA, CGMA, our Senior Vice President and Chief Financial Officer. Pursuant to the agreement, we agreed to pay Mr. Guarino $220,000 per year and a targeted annual bonus of 30% of base salary. We also issued him options to purchase 2,666 shares of our common stock with one-quarter immediately vesting and the remainder vesting over three years. Mr. Guarino's employment agreement automatically renews each year, unless otherwise terminated. Upon termination without "Just Cause", as defined in Mr. Guarino's employment agreement, we would pay Mr. Guarino three months of severance, accrued salary, bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. On December 10, 2020, the Compensation Committee approved an increase in salary for Mr. Guarino to $224,400. On December 10, 2021, the Compensation Committee approved an increase in salary for Mr. Guarino to $231,132. On December 08, 2022, the Compensation Committee approved an increase in salary for Mr. Guarino to $245,000.

Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers outstanding at December 31, 2022. We have never issued Stock Appreciation Rights.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Christopher J. Schaber	666	—	—	$ 301.50	12/04/2023
	666	—	—	$ 225.00	12/04/2024
	933	—	—	$ 169.50	12/30/2025
	4,000	—	—	$ 30.15	12/06/2027
	4,000	—	—	$ 14.55	12/12/2028
	4,000	—	—	$ 14.40	01/01/2029
	4,000	—	—	$ 18.60	12/11/2029
	3,750	250	250	$ 21.75	01/01/2030
	3,000	1,000	1,000	$ 35.10	12/09/2030
	2,750	1,250	1,250	$ 19.20	01/03/2031
	2,000	2,000	2,000	$ 11.70	12/08/2031
	845	—	—	$ 10.35	01/02/2032
	905	2,249	2,249	$ 10.35	01/02/2032
	2,334	6,999	6,999	$ 8.10	12/07/2032
Jonathan Guarino	2,666	—	—	$ 14.55	09/08/2029
	666	—	—	$ 18.60	12/11/2029
	2,003	663	663	$ 35.10	12/09/2030
	1,461	1,872	1,872	$ 11.70	12/08/2031
	1,334	3,999	3,999	$ 8.10	12/07/2032
Oreola Donini	266	—	—	$ 234.00	08/14/2023
	133	—	—	$ 301.50	12/04/2023
	200	—	—	$ 225.00	12/04/2024
	466	—	—	$ 169.50	12/30/2025
	1,333	—	—	$ 40.05	03/30/2027
	2,333	—	—	$ 30.15	12/06/2027
	2,666	—	—	$ 14.55	12/12/2028
	4,000	—	—	$ 18.60	12/11/2029
	3,503	1,163	1,163	$ 35.10	12/09/2030
	2,335	2,331	2,331	$ 11.70	12/08/2031
	1,334	3,999	3,999	$ 8.10	12/07/2032
Richard C. Straube	666	—	—	$ 301.50	01/06/2024
	333	—	—	$ 225.00	12/04/2024
	466	—	—	$ 169.50	12/30/2025
	1,333	—	—	$ 40.05	03/30/2027
	2,333	—	—	$ 30.15	12/06/2027
	2,666	—	—	$ 14.55	12/12/2028
	2,000	—	—	$ 18.60	12/11/2029
	2,003	663	663	$ 35.10	12/09/2030
	1,335	1,331	1,331	$ 11.70	12/08/2031
	1,334	3,999	3,999	$ 8.10	12/07/2032

Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the year ended December 31, 2022.

Name	Fees Earned Paid in Cash [1]	Option Awards [2]	Total
Gregg A. Lapointe	$ 57,500	$ 30,000	$ 87,500
Diane L. Parks	$ 47,500	$ 30,000	$ 77,500
Robert J. Rubin	$ 55,000	$ 30,000	$ 85,000
Jerome B. Zeldis	$ 50,000	$ 30,000	$ 80,000

(1) Directors who are compensated as full-time employees receive no additional compensation for service on our Board of Directors. Each independent director who is not a full-time employee is paid $35,000 annually, on a prorated basis, for their service on our Board of Directors, the chairman of our Audit Committee is paid $15,000 annually, on a prorated basis, and the chairmen of our Compensation and Nominating Committees is paid $10,000 annually, on a prorated basis. Additionally, Audit Committee members are paid $7,500 annually and Compensation and Nominating Committee members are paid $5,000 annually. This compensation is paid quarterly.

(2) We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of our Board of Directors or its committees who are not full-time employees receive an initial grant of fully vested options to purchase 1,000 shares of common stock. Upon re-election to the Board, each Board member will receive stock options with a value of $30,000, calculated using the closing price of the common stock on the trading day prior to the date of the annual meeting of our stockholders, which vest at the rate of 25% per quarter, commencing with the first quarter after each annual meeting of stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The table below provides information regarding the beneficial ownership of the common stock as of March 24, 2023, of (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned **	Percent of Class
Christopher J. Schaber [1]	42,193	1.4 %
Gregg A. Lapointe [2]	9,698	*
Diane L. Parks [3]	8,551	*
Robert J. Rubin [4]	9,499	*
Jerome B. Zeldis [5]	10,734	*
Jonathan Guarino [6]	9,783	*
Oreola Donini [7]	19,487	*
Richard Straube [8]	15,671	*
All directors and executive officers as a group (8 persons)	125,616	4.1 %

(1) Includes 6,010 shares of common stock and options to purchase 36,183 shares of common stock exercisable within 60 days of March 24, 2023. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(2) Includes 492 shares of common stock and options to purchase 9,206 shares of common stock exercisable within 60 days of March 24, 2023. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(3) Includes 996 shares of common stock and options to purchase 7,555 shares of common stock exercisable within 60 days of March 24, 2023. The address of Ms. Parks is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(4) Includes 293 shares of common stock and options to purchase 9,206 shares of common stock exercisable within 60 days of March 24, 2023. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(5) Includes 1,528 shares of common stock and options to purchase 9,206 shares of common stock exercisable within 60 days of March 24, 2023. The address of Dr. Zeldis is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(6) Includes 734 shares of common stock and options to purchase 9,049 shares of common stock exercisable within 60 days of March 24, 2023. The address of Mr. Guarino is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(7) Includes options to purchase 19,487 shares of common stock exercisable within 60 days of March 24, 2023. The address of Dr. Donini is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(8) Includes 534 shares of common stock and options to purchase 15,137 shares of common stock exercisable within 60 days of March 24, 2023. The address of Dr. Straube is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

* Indicates less than 1%.

** Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of March 24, 2023 are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 2,924,491 shares of common stock outstanding as of March 24, 2023.

Equity Compensation Plan Information

In December 2005, our Board of Directors approved the 2005 Equity Incentive Plan, which was approved by stockholders on December 29, 2005. The maximum number of shares of our common stock available for issuance under the 2005 Equity Incentive Plan is 300,000 shares. In April 2015, our Board of Directors approved the 2015 Equity Incentive Plan, which was approved by stockholders on June 18, 2015. On September 22, 2022, the stockholders approved an amendment to the 2015 Plan to increase the maximum numbers of shares of common stock available for issuance under the plan from 2,000,000 to 6,000,000 shares. As of December 31, 2022, there are 5,812,991 shares currently available for future grants under the 2015 Plan.

The following table sets forth certain information, as of December 31, 2022, with respect to the following compensation plans (including individual compensation arrangements) under which our equity securities are authorized for issuance:

- all compensation plans previously approved by our security holders; and
- all compensation plans not previously approved by our security holders.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders [1]	192,273	$ 27.56	5,812,991
Equity compensation plans not approved by security holders	—	—	—
Total	192,273	$ 27.56	5,812,991

(1) Includes our 2005 Equity Incentive Plan and our 2015 Equity Incentive Plan. Our 2005 Equity Incentive Plan expired in 2015 and thus no securities remain available for future issuance under that plan.

Item 13. Certain Relationships and Related Transactions and Director Independence

Related Party Transactions

Our audit committee is responsible for the review, approval and ratification of related party transactions. The audit committee reviews these transactions under our Code of Ethics, which governs conflicts of interests, among other matters, and is applicable to our employees, officers and directors.

We are party to a registration rights agreement with certain stockholders. The agreement provides that the stockholders have the right to require that we register its shares under the Securities Act for sale to the public, subject to certain conditions. The stockholders also have piggyback registration rights, which means that, if not already registered, they have the right to include their shares in any registration that we effect under the Securities Act, subject to specified exceptions. We must pay all expenses incurred in connection with the exercise of these demand registration rights.

We are unable to estimate the dollar value of the registration rights to the holders of these rights. The amount of reimbursable expenses under the agreements depends on a number of variables, including whether registration rights are exercised incident to a primary offering by us, the form on which we are eligible to register such a transaction, and whether we have a shelf registration in place at the time of a future offering.

Other than as described above, the employment agreements and compensation paid to our directors, we did not engage in any transactions with related parties since January 1, 2019. For a discussion of our employment agreements and compensation paid to our directors, see “Item 11. Executive Compensation.”

Director Independence

The Board of Directors has determined that Mr. Lapointe, Ms. Parks, Dr. Rubin, and Dr. Zeldis are “independent” as such term is defined by the applicable listing standards of Nasdaq. Our Board of Directors based this determination primarily on a review of the responses of the Directors to questionnaires regarding their employment, affiliations and family and other relationships.

Item 14. Principal Accountant Fees and Services

The following table highlights the aggregate fees billed during each of the two years ended December 31, 2022 and 2021 by EisnerAmper LLP.

	2022	2021
Audit fees	**$ 153,930**	$ 167,041
Tax fees	**13,335**	13,520
Total	**$ 167,265**	$ 180,561

Audit Fees

This category includes the fees for the examination of our consolidated financial statements, review of our Annual Report on Form 10-K and quarterly reviews of the interim financial statements included in our Quarterly Reports on Form 10-Q.

Tax Fees

This category relates to professional services for tax compliance, tax advice and tax planning.

Other Fees

Our principal accountants did not bill us for any services or products other than as reported above in this Item 14 during each of the two years.

Pre-Approval Policies and Procedures

The audit committee has adopted a policy that requires advance approval of all audit services and permitted non-audit services to be provided by the independent auditor as required by the Exchange Act. The audit committee must approve the permitted service before the independent auditor is engaged to perform it. The audit committee approved all of the services described above in accordance with its pre-approval policies and procedures.

Part IV

Item 15. Exhibits and Financial Statements Schedules

(1) Consolidated Financial Statements:

The financial statements required to be filed by Item 8 of this Annual Report on Form 10-K and filed in this Item 15, are as follows:

(2) Financial Statement Schedules

Schedules are omitted because they are not applicable, or are not required, or because the information is included in the consolidated financial statements and notes thereto.

(3) Exhibits:

2.1	Agreement and Plan of Merger, dated May 10, 2006 by and among the Company, Corporate Technology Development, Inc., Enteron Pharmaceuticals, Inc. and CTD Acquisition, Inc. (incorporated by reference to Exhibit 2.1 included in our Registration Statement on Form SB-2 (File No. 333-133975) filed on May 10, 2006).
3.1	Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2012).
3.2	Amended and Restated By-laws (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended June 30, 2003).
3.3	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2016).
3.4	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on October 7, 2016).
3.5	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 14, 2017).
3.6	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our current report on Form 8-K filed on September 28, 2018).
3.7	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of amendment number 1 to current report on Form 8-K filed on December 3, 2020).
3.8	Amendment to Amended and Restated By-laws (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2020).
3.9	Certificate of Designation of the Series D preferred stock of the Company dated December 27, 2022 (incorporated by reference to Exhibit 3.1 to our Registration Statement on Form 8-A filed on December 27, 2022).
3.10	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation of Soligenix, Inc. (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on February 9, 2023).
4.1	Description of Securities. *
4.2	Registration Rights Agreement, dated December 15, 2020 by and among Soligenix, Inc. and the other parties named therein (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on December 16, 2020).
10.1	License Agreement between the Company and the University of Texas Southwestern Medical Center (incorporated by reference to Exhibit 10.9 included in our Annual Report on Form 10-KSB filed March 30, 2004, as amended, for the fiscal year ended December 31, 2004).
10.2	2005 Equity Incentive Plan, as amended on September 25, 2013 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on September 30, 2013). **
10.3	Form S-8 Registration of Stock Options Plan dated December 30, 2005 (incorporated by reference to our registration statement on Form S-8 filed on December 30, 2005).
10.4	Form S-8 Registration of Stock Options Plan dated June 20, 2014 (incorporated by reference to our registration statement on Form S-8 filed on June 20, 2014).

10.5	Form S-8 Registration of Stock Options Plan dated December 11, 2015 (incorporated by reference to our registration statement on Form S-8 filed on December 14, 2015).
10.6	Employment Agreement dated December 27, 2007, between Christopher J. Schaber, PhD and the Company (incorporated by reference to Exhibit 10.30 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008). **
10.7	Exclusive License Agreement dated November 24, 1998, between Enteron Pharmaceuticals, Inc. and George B. McDonald, MD and amendments (incorporated by reference to Exhibit 10.42 included in our Registration Statement on Form S-1 (File No. 333-157322) filed on February 13, 2009).
10.8	First Amendment to Employment Agreement dated as of July 12, 2011, between the Company and Christopher J. Schaber, PhD (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on July 14, 2011).**
10.9	Amendment to the Exclusive License Agreement dated as of July 26, 2011, between George McDonald, MD and the Company (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on July 28, 2011).
10.10	Amendment No. 2 to the Collaboration and Supply Agreement between the Company, Enteron and Sigma-Tau dated as of December 20, 2012 (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on December 27, 2012). †
10.11	Amendment to Exclusive License Agreement dated as of December 20, 2012 between Enteron and McDonald (incorporated by reference to Exhibit 10.4 of our current report on Form 8-K filed on December 27, 2012).
10.12	Amendment to Consulting Agreement dated as of December 20, 2012 between Enteron and McDonald (incorporated by reference to Exhibit 10.5 of our current report on Form 8-K filed on December 27, 2012).
10.13	Contract HHSO100201300023C dated September 18, 2013 between the Company and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 24, 2013). †
10.14	Contract HHSN272201300030C dated September 24, 2013 by and between the Company and the National Institutes of Health (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 30, 2013). †
10.15	Employment Agreement dated as of January 6, 2014 between the Company and Richard Straube, M.D. (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on January 8, 2014). **
10.16	Asset Purchase Agreement dated September 3, 2014 between the Company and Hy Biopharma, Inc. (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 5, 2014). †
10.17	Registration Rights Agreement dated September 3, 2014 between the Company and Hy Biopharma, Inc. (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on September 5, 2014).
10.18	Contract HHSN272201400039C dated September 17, 2014 by and between the Company and the National Institutes of Health (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 23, 2014). †
10.19	Lease Agreement dated November 21, 2014, between the Company and CPP II, LLC (incorporated by reference to Exhibit 10.42 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014).
10.20	At Market Issuance Sales Agreement dated August 11, 2017 between Soligenix, Inc. and FBR Capital Markets & Co. (incorporated by reference to Exhibit 1.1 included in our Quarter Report on Form 10-Q for the fiscal quarter ended June 30, 2017).

10.21	Form of Registration Rights Agreement dated October 31, 2017 (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on October 31, 2017).
10.22	First Amendment to Employment Agreement dated as of April 1, 2019 between the Company and Richard Straube, M.D. (incorporated by reference to Exhibit 10.30 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018.**
10.23	Soligenix, Inc. 2015 Equity Incentive Plan, as amended on June 18, 2017, September 27, 2018, September 6, 2019 and September 22, 2022. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on September 23, 2022).
10.24	Employment Agreement dated as of September 6, 2019 between the Company and Jonathan L. Guarino (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on September 11, 2019).**
10.25	Second Amendment to Employment Agreement dated as of January 2, 2020, between Soligenix, Inc. and Christopher J. Schaber, PhD (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on January 3, 2020).**
10.26	Amendment No. 1 to At Market Issuance Sales Agreement dated August 28, 2020 between Soligenix, Inc. and B. Riley FBR, Inc. (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on August 28, 2020).
10.27	Third Extension and Amendment to Lease dated July 7, 2020 between CPP II LLC and Soligenix, Inc. (incorporated by reference to Exhibit 10.1 included in our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2020).
10.28	Loan and Security Agreement, dated December 15, 2020. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on December 16, 2020).
10.29	Third Amendment to Employment Agreement dated as of December 10, 2020, between Soligenix, Inc. and Christopher J. Schaber, PhD. (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on December 16, 2020). **
10.30	Form S-8 Registration Statement dated December 11, 2015 relating to Soligenix, Inc. 2015 Equity Incentive Plan (incorporated by reference to our registration statement on Form S-8 filed on October 28, 2022).
21.1	Subsidiaries of the Company. *
23.1	Consent of EisnerAmper LLP. *
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002). *
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002). *
32.1	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

* Filed herewith.
** Indicates management contract or compensatory plan.
† Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SOLIGENIX, INC.
By: /s/ Christopher J. Schaber
Christopher J. Schaber, PhD
Chief Executive Officer and President

Date: March 31, 2023

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated and on the dates indicated.

Name	Capacity	Date
/s/ Christopher J. Schaber Christopher J. Schaber, PhD	Chairman of the Board, Chief Executive Officer and President (principal executive officer)	March 31, 2023
/s/ Gregg A. Lapointe Gregg A. Lapointe, CPA	Director	March 31, 2023
/s/ Diane L. Parks Diane L. Parks, MBA	Director	March 31, 2023
/s/ Robert J. Rubin Robert J. Rubin, MD	Director	March 31, 2023
/s/ Jerome B. Zeldis Jerome B. Zeldis, MD, PhD	Director	March 31, 2023
/s/ Jonathan Guarino Jonathan Guarino, CPA, CGMA	Chief Financial Officer, Senior Vice President, and Corporate Secretary (principal accounting officer)	March 31, 2023

SOLIGENIX, INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

Soligenix, Inc. and Subsidiaries
Consolidated Balance Sheets
As of December 31, 2022 and 2021

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	**$ 13,359,615**	$ 26,043,897
Contracts and grants receivable	**115,130**	138,889
Research and development incentives receivable, current	**104,198**	103,832
Prepaid expenses and other current assets	**274,209**	282,903
Total current assets	**13,853,152**	26,569,521
Security deposit	**22,777**	22,777
Office furniture and equipment, net of accumulated depreciation of $114,766 and $167,848	**18,481**	22,220
Deferred issuance cost	**20,206**	20,266
Right-of-use lease assets	**340,987**	106,155
Research and development incentives receivable, net of current portion	**24,114**	121,238
Other assets	**—**	7,750
Total assets	**$ 14,279,717**	$ 26,869,927
Liabilities, mezzanine equity and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	**$ 3,865,796**	$ 2,925,544
Accrued expenses	**2,307,746**	2,956,545
Accrued compensation	**336,692**	302,936
Lease liabilities, current	**108,948**	106,151
Convertible debt, net of debt discount of $102,309	**9,897,691**	—
Total current liabilities	**16,516,873**	6,291,176
Non-current liabilities:		
Convertible debt, net of debt discount of $143,847	**—**	9,856,153
Lease liabilities, net of current portion	**233,627**	—
Total liabilities	**16,750,500**	16,147,329
Commitments and contingencies		
Mezzanine equity:		
Series D preferred stock, $.001 par value; 50,000 shares authorized, none issued or outstanding as of December 31, 2022, subject to possible redemption at redemption value; liquidation value is $43	43	—
Shareholders' equity (deficit):		
Preferred stock, 300,000 and 350,000 shares authorized as of December 31, 2022 and December 31, 2021, respectively; none issued or outstanding	—	—
Common stock, $.001 par value; 75,000,000 shares authorized; 2,908,578 shares and 2,858,244 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively[(1)]	**2,909**	2,859
Additional paid-in capital	**217,064,964**	216,442,904
Accumulated other comprehensive income	**24,747**	41,942
Accumulated deficit	**(219,563,446)**	(205,765,107)
Total shareholders' equity (deficit)	**(2,470,826)**	10,722,598
Total liabilities, mezzanine equity and shareholders' equity (deficit)	**$ 14,279,717**	$ 26,869,927

(1) Adjusted to reflect the reverse stock split of one-for-fifteen effective February 10, 2023

The accompanying notes are an integral part of these consolidated financial statements.

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Operations
For the Years Ended December 31, 2022 and 2021

	Year Ended December 31,	
	2022	2021
Revenues:		
Licensing revenue	**$ 250,000**	$ —
Contract revenue	**—**	33,351
Grant revenue	**698,911**	790,917
Total revenues	**948,911**	824,268
Cost of revenues	**(550,822)**	(728,640)
Gross profit	**398,089**	95,628
Operating expenses:		
Research and development	**7,944,089**	8,185,850
General and administrative	**6,692,904**	5,008,738
Total operating expenses	**14,636,993**	13,194,588
Loss from operations	**(14,238,904)**	(13,098,960)
Other income (expense):		
Gain on forgiveness of PPP loan	**—**	421,584
Foreign currency transaction loss	**(30,549)**	(39,361)
Interest expense, net	**(822,611)**	(904,502)
Research and development incentives	**132,869**	174,770
Other income	**5,921**	30,754
Total other income (expense)	**(714,370)**	(316,755)
Net loss before income taxes	**(14,953,274)**	(13,415,715)
Income tax benefit	**1,154,935**	864,742
Net loss applicable to common stockholders	**$ (13,798,339)**	$ (12,550,973)
Basic and diluted net loss per share [(1)]	**$ (4.81)**	$ (4.69)
Basic and diluted weighted average common shares outstanding [(1)]	**2,871,345**	2,675,488

(1) Adjusted to reflect the reverse stock split of one-for-fifteen effective February 10, 2023.

The accompanying notes are an integral part of these consolidated financial statements.

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Comprehensive Loss
For the Years Ended December 31, 2022 and 2021

	Year Ended December 31,	
	2022	2021
Net loss	**$ (13,798,339)**	$ (12,550,973)
Other comprehensive income (loss):		
Foreign currency translation adjustments	**(17,195)**	66,279
Comprehensive loss	**$ (13,815,534)**	$ (12,484,694)

The accompanying notes are an integral part of these consolidated financial statements.

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Changes in Mezzanine Equity and Shareholders' Equity (Deficit)
For the Years Ended December 31, 2022 and 2021

	Mezzanine Equity-Series D Preferred Stock		Common Stock		Additional Paid–In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Par Value	Shares	Par Value				
Balance, December 31, 2020	**—**	**$ —**	**2,042,911**	**$ 2,043**	**$ 196,978,256**	**$ (24,337)**	**$ (193,214,134)**	**$ 3,741,828**
Issuance of common stock pursuant to B. Riley At Market Issuance Sales Agreement			811,646	812	19,704,835	—	—	19,705,647
Issuance costs associated with B. Riley At Market Issuance Sales Agreement			—	—	(655,156)	—	—	(655,156)
Issuance of common stock to vendors			1,667	2	27,498	—	—	27,500
Exercise of stock options			2,018	2	25,833	—	—	25,835
Exercise of warrants			2	—	79	—	—	79
Share-based compensation expense			—	—	361,559	—	—	361,559
Foreign currency translation adjustment			—	—	—	66,279	—	66,279
Net loss			—	—	—	—	(12,550,973)	(12,550,973)
Balance, December 31, 2021	**—**	**$ —**	**2,858,244**	**$ 2,859**	**$ 216,442,904**	**$ 41,942**	**$ (205,765,107)**	**$ 10,722,598**
Issuance of common stock pursuant to B. Riley At Market Issuance Sales Agreement			8,542	8	79,346	—	—	79,354
Issuance costs associated with B. Riley At Market Issuance Sales Agreement			—	—	(2,593)	—	—	(2,593)
Declaration of Series D preferred stock for stock dividend	—	43			(43)			(43)
Fractional shares issued in reverse stock split			19,544	20	(20)	—	—	—
Issuance of common stock to vendors			22,248	22	211,981	—	—	212,003
Share-based compensation expense			—	—	333,389	—	—	333,389
Foreign currency translation adjustment			—	—	—	(17,195)	—	(17,195)
Net loss			—	—	—	—	(13,798,339)	(13,798,339)
Balance, December 31, 2022	**—**	**$ 43**	**2,908,578**	**$ 2,909**	**$ 217,064,964**	**$ 24,747**	**$ (219,563,446)**	**$ (2,470,826)**

Adjusted to reflect the reverse stock split of one-for-fifteen effective February 10, 2023.

The accompanying notes are an integral part of these consolidated financial statements.

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2022 and 2021

	2022	2021
Operating activities:		
Net loss	**$ (13,798,339)**	$ (12,550,973)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	**24,562**	34,161
Non-cash lease expense	**112,714**	116,290
Share-based compensation	**333,389**	361,559
Issuance of common stock to vendors for services	**212,003**	27,500
Amortization of deferred issuance costs associated with convertible debt	**41,538**	41,926
Gain on forgiveness of PPP loan	**—**	(421,584)
Change in operating assets and liabilities:		
Licensing, contracts and grants receivable	**23,759**	64,885
Prepaid expenses and other current assets	**8,694**	(57,430)
Research and development incentives receivable	**73,374**	205,237
Operating lease liability	**(111,122)**	(116,290)
Accounts payable and accrued expenses	**396,651**	1,127,259
Accrued compensation	**33,756**	(572,160)
Net cash used in operating activities	**(12,649,021)**	(11,739,620)
Investing activities:		
Purchases of office furniture and equipment	**(13,073)**	(11,789)
Net cash used in investing activities	**(13,073)**	(11,789)
Financing activities:		
Proceeds from issuance of common stock pursuant to B. Riley At Market Issuance Sales Agreement	**79,354**	19,705,647
Costs associated with B. Riley At Market Issuance Sales Agreement	**(2,533)**	(621,899)
Proceeds from the exercise of warrants	**—**	79
Proceeds from the exercises of stock options	**—**	25,835
Costs associated with issuance of convertible debt	**—**	(45,512)
Principal repayment – financing lease	**—**	(6,149)
Net cash provided by financing activities	**76,821**	19,058,001
Effect of exchange rate on cash and cash equivalents	**(99,009)**	60,642
Net (decrease)/increase in cash and cash equivalents	**(12,684,282)**	7,367,234
Cash and cash equivalents at beginning of period	**26,043,897**	18,676,663
Cash and cash equivalents at end of period	**$ 13,359,615**	$ 26,043,897
Supplemental information:		
Cash paid for state income taxes	**$ 16,043**	$ 7,727
Cash paid for interest	**$ 857,411**	$ 668,715
Cash paid for lease liabilities:		
Operating lease	**$ 133,300**	$ 133,300
Financing lease	**$ —**	$ 6,408
Non-cash investing and financing activities:		
Right-of-use assets and lease liabilities recorded	**$ 347,546**	$ —
Deferred issuance cost reclassified to additional paid-in capital	**$ 60**	$ 33,257
Declaration of Series D preferred stock for stock dividend	**$ 43**	$ —

The accompanying notes are an integral part of these consolidated financial statements.

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the "Company") is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. The Company maintains two active business segments: Specialized BioTherapeutics and Public Health Solutions.

The Company's Specialized BioTherapeutics business segment is developing and moving toward commercialization of HyBryte™ (a proposed proprietary name of SGX301 or synthetic (hypericin), a novel photodynamic therapy ("PDT") utilizing safe visible light for the treatment of cutaneous T-cell lymphoma ("CTCL")). With a successful Phase 3 study complete, regulatory approval is being sought and commercialization activities for this product candidate are being advanced initially in the United States ("U.S."). In response to the HyBryte™ new drug application ("NDA") for the treatment of CTCL, the Company recently received a refusal to file ("RTF") letter from the U.S. Food and Drug Administration ("FDA"). The Company is preparing for a meeting, categorized as Type A, to clarify and respond to the issues identified in the RTF letter and to seek additional guidance concerning information that the FDA would require for a resubmitted NDA to be deemed acceptable to file, in order to advance HyBryte™ towards marketing approval and U.S. commercialization. Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, the Company's first-in-class innate defense regulator ("IDR") technology, dusquetide (SGX942) for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203).

The Company's Public Health Solutions business segment includes active development programs for RiVax®, its ricin toxin vaccine candidate and SGX943, its therapeutic candidate for antibiotic resistant and emerging infectious disease, and vaccine programs, including a program targeting filoviruses (such as Marburg and Ebola) and a program developing CiVax™, its vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). The development of the vaccine programs is currently supported by the heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with grant and contract funding from the National Institute of Allergy and Infectious Diseases ("NIAID"), the Biomedical Advanced Research and Development Authority ("BARDA") and the Defense Threat Reduction Agency ("DTRA").

The Company primarily generates revenues under government grants and contracts principally from the National Institutes of Health ("NIH"). The Company has a DTRA subcontract of approximately $600,000 over three years for SGX943, a subcontract of approximately $1.5 million from a NIAID grant over two years for development of CiVax™ and a subcontract of approximately $1.1 million from a U.S. FDA grant over four years for the expanded study of HyBryte™ in the treatment of CTCL. The Company will continue to apply for additional government funding.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with the FDA regulations, and other regulatory authorities, litigation, and product liability.

Liquidity

In accordance with Accounting Standards Codification 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. As of December 31, 2022, the Company had an accumulated deficit of $219,563,446 and a working capital deficit of $2,663,721. During the year ended December 31, 2022, the Company incurred a net loss of $13,798,339 and used $12,649,021 of cash in operating activities. The Company expects to continue to generate losses in the foreseeable future. The Company's liquidity needs will be determined largely by the budgeted operational expenditures incurred in regards to the progression of its product candidates. Management believes that the Company has sufficient resources available to support its development activities and business operations and timely satisfy its obligations as they become due into the third quarter of 2023. The Company does not have sufficient cash and cash equivalents as of the date of filing this Annual Report on

Form 10-K to support its operations for at least the 12 months following the date the financial statements are issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern through 12 months after the date the financial statements are issued.

To alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, the Company plans to secure additional capital, potentially through a combination of public or private equity offerings and strategic transactions, including potential alliances and drug product collaborations, securing additional proceeds from government contract and grant programs, securing additional proceeds available from the sale of shares of the common stock via the At Market Issuance Sales Agreement ("B. Riley Sales Agreement") with B. Riley Securities, Inc. ("B. Riley") and potentially amending the loan agreement with Pontifax to reduce the conversion price in order to allow for conversion of a portion of the debt which will reduce the Company's debt repayments; however, none of these alternatives are committed at this time. There can be no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to it to fund continuing operations, if at all, identify and enter into any strategic transactions that will provide the capital that it will require or achieve the other strategies to alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern. If none of these alternatives are available, or if available, are not available on satisfactory terms, the Company will not have sufficient cash resources and liquidity to fund its business operations for at least the 12 months following the date the financial statements are issued. The failure to obtain sufficient capital on acceptable terms when needed may require the Company to delay, limit, or eliminate the development of business opportunities and its ability to achieve its business objectives and its competitiveness, and its business, financial condition, and results of operations will be materially adversely affected. In addition, market instability, including as a result of geopolitical instability, may reduce the Company's ability to access capital, which could negatively affect its liquidity and ability to continue as a going concern. In addition, the perception that the Company may not be able to continue as a going concern may cause others to choose not to deal with it due to concerns about its ability to meet its contractual obligations.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

As of December 31, 2022, the Company had cash and cash equivalents of $13,359,615 as compared to $26,043,897 as of December 31, 2021, representing a decrease of $12,684,282 or 49%. As of December 31, 2022, the Company had a working capital deficit of $2,663,721 as compared to working capital of $20,278,345 as of December 31, 2021, representing a decrease of $22,942,066 or 113%. The decrease in cash and cash equivalents and working capital was primarily related to cash used in operating activities. The decrease in working capital is also due to the impact of the entire convertible debt balance being classified as a current liability as of December 31, 2022 due to a subjective acceleration clause included in the debt agreement and a potential breach of a cash debt covenant during the twelve month look-forward period from the filing of these financial statements.

Management's business strategy can be outlined as follows:

- Following positive primary endpoint results for the Phase 3 FLASH (Florescent Light Activated Synthetic Hypericin) clinical trial of HyBryte™ in CTCL as well as further statistically significant improvement in response rates with longer treatment (18 weeks compared to 12 and 6 weeks of treatment), meet with the U.S. FDA to discuss the contents of a RTF letter recently issued by the FDA in response to the HyBryte™ NDA for the treatment of CTCL. The Company is preparing for a meeting, categorized as Type A, to clarify and respond to the issues identified in the RTF letter and to seek additional guidance concerning information that the FDA would require for a resubmitted NDA to be deemed acceptable to file, in order to advance HyBryte™ towards marketing approval and U.S. commercialization while continuing to explore ex-U.S. partnership.

- Expanding development of synthetic hypericin under the research name SGX302 into psoriasis with the conduct of a Phase 2a clinical trial, following the positive Phase 3 FLASH study and positive proof-of-concept demonstrated in a small Phase 1/2 pilot study in mild-to-moderate psoriasis patients.

- Following feedback from the United Kingdom ("UK") Medicines and Healthcare products Regulatory Agency ("MHRA") that a second Phase 3 clinical trial of SGX942 in the treatment in oral mucositis would be required to support a marketing authorization; design a second study and attempt to identify a potential partner(s) to continue this development program.

- Continue development of the Company's heat stabilization platform technology, ThermoVax®, in combination with its programs for RiVax® (ricin toxin vaccine), CiVax™ (COVID-19 vaccine) and filovirus vaccines for Ebola, Sudan, and Marburg Viruses, with U.S. government funding support.

- Continue to apply for and secure additional government funding for each of the Company's Specialized BioTherapeutics and Public Health Solutions programs through grants, contracts and/or procurements.

- Pursue business development opportunities for the Company's pipeline programs, as well as explore merger/acquisition strategies.

- Acquire or in-license new clinical-stage compounds for development, as well as evaluate new indications with existing pipeline compounds for development.

The Company's plans with respect to its liquidity management include, but are not limited to, the following:

- The Company has up to $1.7 million in active government grant funding still available as of December 31, 2022 to support its associated research programs through May 2026, provided the federal agencies do not elect to terminate the grants for convenience. The Company plans to submit additional contract and grant applications for further support of its programs with various funding agencies. However, there can be no assurance that the Company will obtain additional governmental grant funding.

- The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future.

- The Company will continue to pursue Net Operating Loss ("NOL") sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program if available.

- The Company plans to pursue potential partnerships for pipeline programs as well as continue to explore merger and acquisition strategies. However, there can be no assurances that the Company can consummate such transactions.

- The Company has up to $26.6 million remaining from the B. Riley Sales Agreement as of March 24, 2023 under the prospectus supplement updated August 13, 2021. The Company is currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, the Company is limited to selling no more than one-third of the aggregate market value of the equity held by non-affiliates, or the public float, during any 12-month period, and as of March 24, 2023, the Company has approximately $6.6 million remaining that is permitted to be sold under the Form S-3 pursuant to General Instruction I.B.6. If the Company's public float increases, the Company will have additional availability under such limitations, and if the Company's public float increases to $75 million or more, the Company will no longer be subject to such limitations. There can be no assurance that the Company's public float will increase or that the Company will no longer be subject to such limitations.

- The Company may seek additional capital in the private and/or public equity markets, to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company is evaluating additional equity/debt financing opportunities on an ongoing basis and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

Reverse Stock Split

On February 9, 2023, the Company completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of one-for-fifteen, whereby, every fifteen shares of the Company's issued and outstanding common stock was converted automatically into one issued and outstanding share of common stock without any change in the par value per share. No fractional shares were issued as a result of the reverse stock split. Any fractional shares that would otherwise have resulted from the reverse stock split were rounded up to the next whole number. The Company's common stock began trading on The NASDAQ Capital Market on a reverse split basis at the market opening on February 10, 2023. All share and per share data have been restated to reflect this reverse stock split.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include Soligenix, Inc., and its wholly and majority owned subsidiaries. All significant intercompany accounts and transactions have been eliminated as a result of consolidation.

Reclassifications

Certain amounts in the statement of operations for the year ended December 31, 2021 have been reclassified to conform to the current year presentation.

Operating Segments

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision-making group, in deciding how to allocate resources to an individual segment and in assessing the performance of the segment. The Company divides its operations into two operating segments: Specialized BioTherapeutics and Public Health Solutions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

Licensing, Contracts and Grants Receivable

Contracts and grants receivable consist of amounts due from various grants from the NIH and contracts from NIAID, an institute of NIH, for costs incurred prior to the period end under reimbursement contracts. The amounts were billed to the respective governmental agencies in the month subsequent to period end and collected shortly thereafter. Accordingly, no allowance for doubtful accounts has been established. If amounts become uncollectible, they are charged to operations.

Licensing receivables consist of amounts billed to customers pursuant to contracts with those customers. No allowance for doubtful accounts has been established for licensing receivables as all amounts billed were collected shortly thereafter.

Website Development Costs

In June 2019, the Company capitalized website development costs of $46,500 in accordance with FASB Codification ASC 350-50 "Accounting for Web Site Development Costs." The Company began amortizing the website development costs on a straight-line basis over three years, the estimated useful life of the website. The Company reviews its capitalized website development costs periodically for impairment. Website amortization expense for 2022 and 2021 was $7,750 and $15,500, respectively, and accumulated amortization was $46,500 and $38,750, respectively, as of December 31, 2022 and 2021. Website development costs were included in other assets in the accompanying consolidated balance sheets.

Impairment of Long-Lived Assets

Office furniture and equipment, right of use assets and website development costs with finite lives are evaluated and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

The Company did not record any impairment of long-lived assets for the years ended December 31, 2022 and 2021.

Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to the Company on December 31, 2022 and 2021. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

- Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

- Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

- Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, licensing, contracts and/or grants receivable, research and development incentives receivable, accounts payable, accrued expenses, and accrued compensation approximate their fair value based on the short-term maturity of these instruments.

The carrying amount reported in the consolidated balance sheets for convertible debt approximates its fair value based on its interest rate and maturity date.

Revenue Recognition

The Company’s revenues include revenues generated from government contracts and grants. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and

management fees. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs reimbursable internal expenses that are related to the government contracts and grants.

The Company also records revenue from contracts with customers in accordance with Accounting Standards Codification Topic 606 ("ASC 606"), *Revenue From Contracts with Customers*. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Certain amounts received from or billed to customers in accordance with contract terms are deferred and recognized as future performance obligations are satisfied. All amounts earned under contracts with customers other than sales-based royalties are classified as licensing revenue. Sales-based royalties under the Company's license agreements would be recognized as royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue.

Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, *Research and Development*. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, share-based compensation, employee benefits, equipment depreciation and allocation of various corporate costs.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon issuance). Stock options issued to employees generally vest 25% on the grant date, then 25% each subsequent year for a period of three years. These options have a ten year life for as long as the individuals remain employees or directors. In general, when an employee or director terminates their position, the options will expire within three months, unless otherwise extended by the Board.

From time to time, the Company issues restricted shares of common stock to vendors and consultants as compensation for services performed under the Company's 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of stock options, restricted stock, deferred stock and unrestricted stock to the Company's employees and non-employees (including consultants). The shares issued under the 2015 Plan are registered on Form S-8 (SEC File No. 333-208515). However, as shares of common stock are not covered by a reoffer prospectus, the certificates reflecting such shares reflect a Securities Act of 1933, as amended restrictive legend. Stock compensation expense for equity-classified awards to non-employees is measured on the date of grant and is recognized when the services are performed.

The fair value of options issued during the years ended December 31, 2022 and 2021 was estimated using the Black-Scholes option-pricing model and the following assumptions:

- a dividend yield of 0%;
- an expected life of 4 years;
- volatility of 84% - 87% for 2022 and 2021; and

- risk-free interest rates ranging from 1.12% to 4.51% in 2022 and 0.27% to 1.13% in 2021.

The fair value of each option grant made during 2022 and 2021 was estimated on the date of each grant and recognized as share-based compensation expense ratably over the option vesting periods, which approximates the service period.

Foreign Currency Transactions and Translation

In 2018, the Company changed the status of a wholly-owned subsidiary in the UK from inactive to active and incurred expenditures in multiple currencies including the U.S. dollar, the British Pound and the Euro to fund its clinical trial operations in the UK and select countries in Europe. In accordance with FASB ASC 830 *Foreign Currency Matters*, the UK subsidiary expresses its U.S. dollar and Euro denominated transactions in its functional currency, the British Pound, with related transaction gains or losses included in net loss. On a quarterly basis, the financial statements of the UK subsidiary are translated into U.S. dollars and consolidated into the Company's financials, with related translation adjustments reported as a cumulative translation adjustment ("CTA"), which is a component of accumulated other comprehensive loss. In 2022 and 2021, the Company recognized foreign currency transaction losses of $30,549 and $39,361, respectively, in the accompanying consolidated statements of operations.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The Company recognized an income tax benefit of $1,154,935 and $864,742 from the sale of 2020 and 2019 New Jersey NOL carryforwards during the years ended December 31, 2022 and 2021, respectively. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2022 and 2021. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2022 or 2021.

Research and Development Incentive Income and Receivable

The Company recognizes other income from UK research and development incentives when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The small or medium sized enterprise ("SME") research and development tax relief program supports companies that seek to research and develop an advance in their field and is governed through legislative law by HM Revenue & Customs as long as specific eligibility criteria are met.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the SME research and development tax relief program described above. At each period end, management estimates the refundable tax offset available to the Company based on available information at the time. As the tax incentives may be received without regard to an entity's actual tax liability, they are not subject to accounting for income taxes. As a result, amounts realized under the SME research and development tax relief program are recorded as a component of other income.

The research and development incentive receivable represents an amount due in connection with the above-described tax relief program. The Company has recorded a research and development incentive receivable of approximately $128,000 and $225,000 as of December 31, 2022 and 2021, respectively in the consolidated balance sheets.

The following table shows the change in the UK research and development incentives receivable from December 31, 2021 to December 31, 2022:

	Current	Long-Term	Total
Balance at December 31, 2021	$ 103,832	$ 121,238	$ 225,070
UK research and development incentives, transfer	121,238	(121,238)	—
UK research and development incentives	—	24,963	24,963
Additional 2020 incentive earned	107,906	—	107,906
UK research and development incentives cash receipt	(209,166)	—	(209,166)
Foreign currency translation	(19,612)	(849)	(20,461)
Balance at December 31, 2022	$ 104,198	$ 24,114	$ 128,312

Loss Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

The following table summarizes potentially dilutive adjustments to the number of common shares which were excluded from the diluted calculation because their effect would be anti-dilutive due to the losses in each period:

	December 31, 2022	December 31, 2021
Common stock purchase warrants	**667**	221,872
Stock options	**192,273**	140,996
Convertible debt	**162,602**	162,602
Total	**355,542**	525,470

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions such as the fair value of warrants and stock options and to accrue for clinical trials in process that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Note 3. Leases

The Company classifies a lease for its office space at 29 Emmons Drive, Suite B-10 in Princeton, New Jersey as an operating lease, and recorded a related right-of-use lease asset and lease liability accordingly. Pursuant to an amendment executed on June 21, 2022, the lease has been extended to October 2025. The current rent of $11,108 per month will be maintained until November 2023 when it will be increased to $11,367 and then will increase to $11,625 in November 2024 where it will remain until expiration. As of December 31, 2022 and 2021, the Company's consolidated balance sheets included a right-of-use lease asset of $340,987 and $106,155 for the office space, respectively. The Company's consolidated balance sheets as of December 31, 2022 and 2021 included corresponding lease liabilities of $342,575 and $106,151 for the office space, respectively.

The following represents a reconciliation of contractual lease cash flows to the right-of-use lease asset and liability recognized in the financial statements:

	Operating Lease
Contractual cash payments for the remaining lease term as of December 31, 2022	
2023	$ 133,817
2024	136,917
2025	116,250
Total	**$ 386,984**
Discount rate applied	8.47 %
Remaining lease term (months) as of December 31, 2022	**34**
Right-of-use lease asset:	
Right-of-use lease asset, January 1, 2021	$ 222,445
Less: reduction/amortization	116,290
Right-of-use lease asset, December 31, 2021	106,155
New lease extension June 21, 2022	347,546
Reduction/amortization	112,714
Right of use lease asset, December 31, 2022	**$ 340,987**
Lease liability:	
Lease liability, January 1, 2021	$ 222,441
Less: repayments	116,290
Lease liability, December 31, 2021	106,151
New lease extension June 21, 2022	347,546
Less: repayments	111,122
Lease liability, December 31, 2022	**$ 342,575**
Lease expense for the year ended December 31, 2021:	
Lease expense	$ 133,300
Total	**$ 133,300**
Lease expense for the year ended December 31, 2022:	
Lease expense	$ 134,892
Total	**$ 134,892**

Note 4. Accrued Expenses

The following is a summary of the Company's accrued expenses:

	December 31,	
	2022	2021
Clinical trial expenses	**$ 1,884,117**	$ 2,625,779
Other	**423,629**	330,766
Total	**$ 2,307,746**	$ 2,956,545

Note 5. Debt

In December 2020, the Company entered into a $20 million convertible debt financing agreement with Pontifax Medison Debt Financing ("Pontifax"), the healthcare-dedicated venture and debt fund of the Pontifax life science funds. Under the terms of the agreement with Pontifax, the Company had access to up to $20 million in convertible debt financing in three tranches, which will mature on June 15, 2025 and had an interest-only period for the first two years with a fixed interest rate of 8.47% on borrowed amounts and an interest rate of 1% on amounts available but not borrowed as an unused line of credit fee. After the interest-only period, the outstanding principal is to be repaid in quarterly payments of $1 million each commencing in the first quarter of 2023. The agreement is secured by a lien covering substantially all of the Company's

assets, other than intellectual property. The agreement contains customary representations, warranties and covenants, including covenants by the Company limiting additional indebtedness, liens, including on intellectual property, guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates and fundamental changes. Affirmative covenants include, among others, covenants requiring the Company to protect and maintain its intellectual property and comply with all applicable laws, deliver certain financial reports, maintain a minimum cash balance and maintain its insurance coverage. As of December 31, 2022, the Company projected a violation of the minimum cash balance requirement during 2023 and the debt agreement contains a subjective acceleration clause, therefore has classified the entire debt balance as a current liability.

Upon the closing of this transaction, the Company accessed the first tranche of $10 million, had the option to draw the second tranche of $5 million at any time during the initial 12 months of the loan and the third tranche of $5 million upon filing of the HyBryte™ NDA, subject to certain conditions. The Company elected to let the options to borrow both the second and third tranches expire as of December 15, 2021 and March 15, 2022, respectively.

Interest expense incurred during the years ended December 31, 2022 and 2021 was $847,000 and $894,808, respectively. Interest expense paid during the years ended December 31, 2022 and 2021 was $857,411 and $668,715, respectively.

Pontifax may elect to convert the outstanding loan drawn into shares of the Company's common stock at any time prior to repayment at a conversion price of $61.50 per share. The Company also has the ability to force the conversion of the loan into shares of the Company's common stock at the same conversion price, subject to certain conditions.

Annual principal and interest payments due, according to the agreement's contractual terms, assuming no conversion is as follows:

Year	Principal	Interest	Total
2023	$ 4,000,000	$ 634,438	$ 4,634,438
2024	4,000,000	295,638	4,295,638
2025	2,000,000	21,349	2,021,349
Total	$ 10,000,000	$ 951,425	$ 10,951,425

Note 6. Income Taxes

The income tax benefit consisted of the following for the years ended December 31, 2022 and 2021:

	2022	2021
Federal	**$ —**	$ —
Foreign	**—**	—
State	**(1,154,935)**	(864,742)
Income tax benefit	**$ (1,154,935)**	$ (864,742)

The significant components of the Company's deferred tax assets and liabilities at December 31, 2022 and 2021 are as follows:

	2022	2021
Net operating loss carry forwards	**$ 27,252,000**	$ 28,065,000
Orphan drug and research and development credit carry forwards	**8,837,000**	8,605,000
Equity based compensation	**285,000**	264,000
Intangibles	**1,696,000**	1,953,000
Capitalized research and development (Section 174)	**1,832,000**	—
Lease liability	**96,000**	30,000
Total	**39,998,000**	38,917,000
Valuation allowance	**(39,902,000)**	(38,887,000)
Net deferred tax assets	**96,000**	30,000
Right of use asset	**(96,000)**	(30,000)
Total gross deferred tax liabilities	**(96,000)**	(30,000)
Net deferred tax assets	**$ —**	$ —

The Company had gross NOLs at December 31, 2022 of approximately $124.0 million for federal tax purposes, approximately $13.2 million for state tax purposes and approximately $1.4 million for foreign tax purposes. Federal losses generated in 2018 or later will carry forward indefinitely. In addition, the Company has approximately $8.8 million of various tax credits which credit the Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carryforwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. federal jurisdiction, and various state and local jurisdictions. During the years ended December 31, 2022 and 2021 in accordance with the State of New Jersey's Technology Business Tax Certificate Program, which allowed certain high technology and biotechnology companies to sell unused NOL carryforwards to other New Jersey-based corporate taxpayers, the Company sold New Jersey NOL carry forwards, resulting in the recognition of $1,154,935 and $864,742, respectively, of income tax benefit, net of transaction costs. The Company has not yet sold its 2022 New Jersey NOLs but may do so in the future. There can be no assurance as to the continuation or magnitude of this program in the future.

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2022 and 2021 were as follows:

	2022	2021
Federal tax at statutory rate	**(21.0)**%	(21.0)%
State tax benefits, plus sale of NJ NOL, net of federal benefit	**(2.4)**	(7.6)
Foreign tax rate difference	**0.2**	0.1
Orphan drug and research and development credits	**(3.9)**	(4.3)
Permanent differences	**3.1**	1.3
Foreign NOL adjustments	**0.4**	0.6
Expiration of tax attributes	**9.1**	4.9
Change in valuation allowance	**6.8**	19.6
Income tax benefit	**(7.7)**%	(6.4)%

Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2022, there were no uncertain positions. The Company's U.S. federal and state net operating losses have occurred since its inception and as such, tax years subject to potential tax examination could apply from 2011, the earliest year with a net operating loss carryover, because the utilization of net operating losses from prior years opens the relevant year to audit by the IRS and/or state taxing authorities. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the years ended December 31, 2022 and 2021.

Note 7. Shareholders' Equity (Deficit)

Preferred Stock

The Company has 350,000 shares of preferred stock authorized, of which 50,000 were designated as Series D preferred stock during the year ended December 31, 2022.

Series D Preferred Stock

On December 21, 2022, the Board of Directors of the Company declared a dividend for the stockholders of record on January 3, 2023. The dividend consists of one one-thousandth of a share of Series D preferred stock, par value $0.001 per share, for each outstanding share of the Company's common stock. The Series D preferred stock has the following rights and restrictions:

General; Transferability - Series D preferred stock shares will be in book-entry form without certificates. Transfers can only happen alongside common stock transfers, with 1/1,000th of a Series D preferred stock share transferred for each common stock share transferred.

Voting Rights - Each Series D preferred stock share gives the holder 1,000,000 votes. If a shareholder owns a fraction of a share, they will have a proportional number of votes.

Series D preferred stock and common stock shares only vote together on two specific matters:

1. Any plan to change the Company's Certificate of Incorporation for a reverse stock split.
2. Any plan to delay a stockholders' meeting to vote on a reverse stock split (the "Adjournment Proposal").

When voting on the reverse stock split or the Adjournment Proposal, each Series D preferred stock share (or fraction of a share) will vote the same way as the common stock share it was issued from.

Dividend Rights - The holders of Series D preferred stock will not be entitled to receive dividends of any kind.

Liquidation Preference - If the Company undergoes liquidation, dissolution, or winding up, Series D preferred stock has priority over common stock for asset distribution. In such a situation, Series D preferred stockholders will receive a cash payment of $0.001 per share before any distribution is made to common stockholders.

Redemption - If Series D preferred stockholders do not attend or vote by proxy at a meeting for the reverse stock split and Adjournment Proposal, their shares will be automatically redeemed by the Company. If any Series D preferred stock remains after this redemption, it can be redeemed in one of two ways:

1. The Board decides to redeem the shares at a time and date of their choosing.
2. The shares will be automatically redeemed when the Company's stockholders approve the reverse stock split during a meeting for this purpose.

When Series D preferred stock is redeemed, stockholders receive a cash payment based on the number of shares they own. For every 100 whole shares redeemed, the stockholder will get $0.10 in cash.

The Series D preferred stock shares are classified as mezzanine equity as of December 31, 2022 since they are not mandatorily redeemable but are redeemable based on an event not entirely controlled by the Company.

Common Stock

The following items represent transactions in the Company’s common stock for the year ended December 31, 2022:

- The Company issued a vendor 5,377 shares of fully vested common stock with a fair value of $9.30 per share on February 7, 2022.
- The Company issued a vendor 6,411 shares of fully vested common stock with a fair value of $7.80 per share on May 6, 2022.
- The Company issued a vendor 3,664 shares of fully vested common stock with a fair value of $13.65 per share on August 5, 2022.
- The Company issued a vendor 1,667 shares of fully vested common stock with a fair value of $7.20 per share on October 4, 2022.
- The Company issued a vendor 5,129 shares of fully vested common stock with a fair value of $9.75 per share on November 7, 2022.
- The Company issued 8,542 shares of common stock pursuant to the B. Riley Sales Agreement at a weighted average price of $9.29 per share.

The following items represent transactions in the Company's common stock for the year ended December 31, 2021:

- The Company issued 2 shares of common stock as a result of a warrant exercise. The weighted average exercise price per share was $59.25.

- The Company issued 811,646 shares of common stock pursuant to the B. Riley Sales Agreement at a weighted average price of $24.28 per share.

- The Company issued 2,018 shares of common stock as a result of option exercises. The weighted average exercise price per share was $12.81.

- The Company issued a vendor 1,667 shares of fully vested common stock with a fair value of $16.50 per share on September 29, 2021.

All issuances of the Company's common stock for the years ended December 31, 2022 and 2021 described above, other than shares issued under the B. Riley Sales Agreement and the issuance to vendors, were issued under the 2015 Plan and are registered on a Registration Statement on Form S-8 (SEC File No. 333-208515). However, as shares of common stock are not covered by a reoffer prospectus, the certificates evidencing such shares reflect a Securities Act of 1933, as amended, restrictive legend. The shares issued under the B. Riley Sales Agreement were registered on a Registration Statement on Form S-3 (SEC File No. 333-239928).

The issuance of the Company's common stock to vendors as described above was exempt under Section 4(a)(2) of the Securities Act of 1933, as amended. The vendors are knowledgeable, sophisticated and experienced in making investment decisions of this kind and received adequate information about the Company or had adequate access to information about the Company. The vendors represented to the Company that the vendors are not "consultants" for purposes of Nasdaq Listing Rule 5635(c).

B. Riley At Market Issuance Sales Agreement

On August 11, 2017, the Company entered into the B. Riley Sales Agreement to sell shares of the Company's common stock from time to time, through an "at-the-market" equity offering program under which B. Riley acts as sales agent. Under the B. Riley Sales Agreement, the Company sets the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales may be requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. The B. Riley Sales Agreement provides that B. Riley is entitled to compensation for its services in an amount equal to 3% of the gross proceeds from the sale of shares sold under the B. Riley Sale Agreement. The Company has no obligation to sell any shares under the B. Riley Sales Agreement, and may suspend solicitation and offers under the B. Riley Sales Agreement at any time. The B. Riley Sales Agreement expires on December 31, 2023.

The Company's shelf registration statement on Form S-3 (File No. 333- 217738) filed on May 5, 2017 (the "May 2017 Registration Statement") with the U.S. Securities and Exchange Commission (the "SEC") expired on August 10, 2020, but was available to be utilized for a period up to six months or until a new shelf registration statement was declared effective, whichever occurred first. All sales under the B. Riley Sales Agreement from August 11, 2017 through August 10, 2020 were made pursuant to the May 2017 Registration Statement.

All sales of common stock made pursuant to the B. Riley Sales Agreement since the expiration of the May 2017 Registration Statement have been, and future sales will be, made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333- 239928) filed on July 17, 2020 (the "July 2020 Registration Statement") with the SEC, and any amendments thereto, the base prospectus filed as part of such registration statement, and any prospectus supplements. The July 2020 Registration Statement was declared effective on August 28, 2020.

On August 13, 2021, the Company filed a prospectus supplement relating to the B. Riley Sales Agreement to offer and sell shares of Company common stock having an aggregate offering price of up to $30 million under the July 2020 Registration Statement. As of March 24, 2023, there was $26.6 million available for the sale of common stock under the B. Riley Sales Agreement. The Company is currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, the Company is limited to selling no more than one-third of the aggregate market value of the equity held by non-

affiliates, or the public float, during any 12-month period, and as of March 24, 2023, the Company has approximately $6.6 million remaining that is permitted to be sold under the Form S-3 pursuant to General Instruction I.B.6. If the Company's public float increases, the Company will have additional availability under such limitations, and if the Company's public float increases to $75 million or more, the Company will no longer be subject to such limitations. There can be no assurance that the Company's public float will increase or that the Company will no longer be subject to such limitations.

Note 8. Stock Option Plans and Warrants to Purchase Common Stock

Stock Option Plans

The Amended and Restated 2005 Equity Incentive Plan ("2005 Plan") was replaced by the 2015 Plan, which was approved in June 2015. No securities are available for future issuance under the 2005 Plan. In September 2022, the stockholders approved an amendment to the 2015 Plan to increase the maximum numbers of shares of common stock available for issuance under the plan by 4,000,000 shares. As of December 31, 2022, there are 5,812,991 shares currently available for grants under the 2015 Plan. The plan is divided into four separate equity programs:

1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of common stock,

2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock,

3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and

4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant.

Shares available for grant under the 2015 Plan were as follows:

Shares available for grant at January 1, 2022	1,866,719
Modification to Plan	4,000,000
Options granted	(55,730)
Options forfeited	2,002
Options exercised	—
Shares available for grant at December 31, 2022	5,812,991

Activity under the 2005 Plan and the 2015 Plan for the years ended December 31, 2022 and 2021

	Options	Weighted Average Exercise Price
Balance outstanding at December 31, 2020	128,858	$ 44.41
Granted	32,925	13.68
Forfeited	(15,982)	54.61
Cancelled	(2,787)	11.70
Exercised	(2,018)	12.81
Balance outstanding at December 31, 2021	140,996	$ 37.12
Granted	55,730	8.85
Forfeited	(3,908)	107.83
Cancelled	(545)	11.70
Exercised	—	—
Balance outstanding at December 31, 2022	192,273	$ 27.56

As of December 31, 2022, there were 133,794 options exercisable with a weighted average exercise price of $34.47 and a weighted average remaining contractual term of 7.05 years. As of December 31, 2022, there were 192,273 options

outstanding with a weighted average remaining term of 7.90 years. Options outstanding as of December 31, 2022 had no intrinsic value.

The Company awarded 55,730 and 32,925 stock options during the years ended December 31, 2022 and 2021, respectively, which had a weighted average grant date fair value per share of $5.57 and $8.40, respectively. The weighted-average exercise price, by price range, for outstanding options to purchase common stock at December 31, 2022 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Options	Exercisable Options
$8.10 - $40.05	8.16	183,250	124,771
$111.00 - $234.00	2.99	6,309	6,309
$301.50 - $339.00	1.34	2,714	2,714
Total	7.90	192,273	133,794

The Company's share-based compensation expense for the years ended December 31, 2022 and 2021 was recognized as follows:

Share-based compensation	2022	2021
Research and development	$ 142,879	$ 158,478
General and administrative	190,510	203,081
Total	$ 333,389	$ 361,559

At December 31, 2022, the total compensation cost for stock options not yet recognized was approximately $427,000 and will be expensed over the next three years.

Warrants to Purchase Common Stock

Warrant activity for the years ended December 31, 2022 and 2021 was as follows:

	Warrants	Weighted Average Exercise Price
Balance at December 31, 2020	382,099	$ 44.47
Granted	—	—
Exercised	(2)	59.25
Expired	(160,225)	59.25
Balance at December 31, 2021	221,872	$ 33.79
Granted	—	—
Exercised	—	—
Expired	(221,205)	33.81
Balance at December 31, 2022	667	$ 29.25

The remaining life, by grant date, for outstanding warrants at December 31, 2022 was:

Grant Date	Exercise Price	Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
March 29, 2018	$ 29.25	0.24	667	667

Note 9. Concentrations

At December 31, 2022 and 2021, the Company had deposits in major financial institutions that exceeded the amount under protection by the Securities Investor Protection Corporation ("SIPC"). Currently, the Company is covered up to $250,000 by the SIPC and at times maintains cash balances in excess of the SIPC coverage.

Note 10. Commitments and Contingencies

The Company has commitments of approximately $230,000 as of December 31, 2022 over the next five years for several licensing agreements with partners and universities. Additionally, the Company has collaboration and license agreements, which upon clinical or commercialization success, may require the payment of milestones of up to approximately $13.2 million, royalties on net sales of covered products ranging from 2% to 3%, sub-license income royalties on covered products up to 15% and sub-license global net sales royalties on covered products ranging from 1.5% to 2.5%, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

The Company currently leases approximately 6,200 square feet of office space at 29 Emmons Drive, Suite B-10 in Princeton, New Jersey. This office space currently serves as the Company's corporate headquarters, and both of the Company's business segments (Specialized BioTherapeutics and Public Health Solutions), operate from this space. Pursuant to an amendment on June 21, 2022, the lease has been extended from November 2022 to October 2025. The current rent is approximately $11,108 per month and will remain so through October 2023. The rent for lease periods starting November 2023 and November 2024 is approximately $11,367 per month and $11,625 per month, respectively.

On September 3, 2014, the Company entered into an asset purchase agreement with Hy Biopharma, Inc. ("Hy Biopharma") pursuant to which the Company acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma's synthetic hypericin product. As consideration for the assets acquired, the Company paid $275,000 in cash and issued 12,328 shares of common stock with a fair value based on the Company's stock price on the date of grant of $3.75 million. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in the Company's research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the U.S. In March 2020, the Company issued 130,413 fully vested shares of common stock to Hy Biopharma as payment for achieving a milestone: the Company determining the Phase 3 clinical trial of HyBryte™ to be successful in the treatment of CTCL. The number of shares of common stock issued to Hy Biopharma was calculated using an effective price of $38.34 per share, based upon a formula set forth in the purchase agreement.

Provided the sole remaining future success-oriented milestone of FDA approval is attained, the Company will be required to make an additional payment of $5.0 million, if and when achieved. Such payment will be payable in restricted securities of the Company provided such number of shares does not exceed 19.9% ownership of the Company's outstanding stock. As of December 31, 2022, no other milestone or royalty payments have been paid or accrued.

In January 2020, the Company's Board of Directors authorized the amendment of Dr. Schaber's employment agreement to increase the number of shares of the Company's common stock from 334 to 33,334 issuable to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by its Board of Directors whereby, directly or indirectly, a majority of its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party.

As a result of the above agreements, the Company has future contractual obligations over the next five years as follows:

Year	Research and Development	Property and Other Leases	Total
2023	$ 46,000	$ 133,817	$ 179,817
2024	46,000	136,917	182,917
2025	46,000	116,250	162,250
2026	46,000	—	46,000
2027	46,000	—	46,000
Total	$ 230,000	$ 386,984	$ 616,984

Contingencies

The Company follows subtopic 450-20 of the FASB Accounting Standards Codification to report accounting for contingencies. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company but which will only be resolved when one or more future events occur or fail to occur. The Company assesses

such contingent liabilities, and such assessment inherently involves an exercise of judgment. A liability is only recorded if management determines that it is both probable and reasonably estimable.

COVID-19

Based on the current outbreak of SARS-CoV-2, the pathogen responsible for COVID-19, which has already had an impact on financial markets, there could be additional repercussions to the Company's operating business, including but not limited to, the sourcing of materials for product candidates, manufacture of supplies for preclinical and/or clinical studies, delays in clinical operations, which may include the availability or the continued availability of patients for trials due to such things as quarantines, conduct of patient monitoring and clinical trial data retrieval at investigational study sites.

COVID-19 affected the Company's operations but did not have a material impact on the Company's business, operating results, financial condition or cash flows as of and for the year ended December 31, 2022.

The future impact of the outbreak is highly uncertain and cannot be predicted, and the Company cannot provide any assurance that the outbreak will not have a material adverse impact on the Company's operations or future results or filings with regulatory health authorities. The extent of the impact to the Company, if any, will depend on future developments, including actions taken to contain the coronavirus.

Emergent BioSolutions Legal Proceedings

On July 1, 2020, the Company filed a demand for arbitration against Emergent BioSolutions, Inc. and certain of its subsidiaries (collectively, "Emergent") with the American Arbitration Association in Mercer County, New Jersey. The Company alleges in the arbitration various breaches of contracts and warranties as well as acts of fraud. Emergent has answered that demand for arbitration denying the allegations and asserting affirmative defenses. The Company presented its case at an arbitration hearing over 12 days in January 2022. Following submission of post-hearing briefs, the arbitration panel heard closing oral arguments in April 2022. The Company sought to recover damages in excess of $19 million from Emergent.

On July 6, 2022, the American Arbitration Association entered a final decision in connection with this arbitration. Despite the arbitration panel ruling that Emergent had committed a number of breaches of the parties' contracts, the panel did not award monetary damages to the Company. On September 30, 2022, the Company filed a petition to vacate the arbitration decision with the Delaware Court of Chancery, requesting that the Court vacate the arbitration decision and remand the matter to the arbitration panel for rehearing. The Company cannot offer any assurances as to any result of its challenge of the arbitration decision or that the Company will recover any damages from Emergent (see Part I, Item 3 – Legal Proceedings).

The Company has received invoices from Emergent related to the above matter. No accrual has been made for these invoices as management deems them invalid and not probable of being required to pay them based on the numerous breaches sited in the arbitration. These invoices total approximately $331,000.

Note 11. Operating Segments

The Company maintains two active operating segments: Specialized BioTherapeutics and Public Health Solutions. Each segment includes an element of overhead costs specifically associated with its operations, with its corporate shared services group responsible for support functions generic to both operating segments.

	For the Years Ended December 31,	
	2022	2021
Revenues		
Specialized BioTherapeutics	**$ 31,929**	$ —
Public Health Solutions	**916,982**	824,268
Total	**$ 948,911**	$ 824,268
(Loss) Income from Operations		
Specialized BioTherapeutics	**$ (7,614,988)**	$ (7,216,450)
Public Health Solutions	**26,612**	(542,270)
Corporate	**(6,650,528)**	(5,340,240)
Total	**$ (14,238,904)**	$ (13,098,960)
Amortization and Depreciation Expense		
Specialized BioTherapeutics	**$ 10,087**	$ 7,804
Public Health Solutions	**1,681**	1,301
Corporate	**12,794**	25,056
Total	**$ 24,562**	$ 34,161
Other (Expense) Income, Net		
Specialized BioTherapeutics	**$ 102,320**	$ 135,409
Corporate	**(816,690)**	(452,164)
Total	**$ (714,370)**	$ (316,755)
Share-Based Compensation		
Specialized BioTherapeutics	**$ 138,075**	$ 136,594
Public Health Solutions	**4,804**	21,884
Corporate	**190,510**	203,081
Total	**$ 333,389**	$ 361,559

	As of December 31,	
	2022	2021
Identifiable Assets		
Specialized BioTherapeutics	**$ 103,742**	$ 128,645
Public Health Solutions	**121,290**	146,296
Corporate	**14,054,685**	26,594,986
Total	**$ 14,279,717**	$ 26,869,927

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Soligenix, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Soligenix, Inc. and Subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, comprehensive loss, changes in mezzanine equity and shareholders' equity (deficit), and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022 and 2021, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and expects to incur losses for the foreseeable future, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrual for Clinical Trial Expenses

As described in Note 2 to the financial statements, the Company is required to estimate at each balance sheet date its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and

under clinical site agreements in connection with conducting clinical trials. The Company recorded clinical trial accruals of $1.9 million, which are included in accrued expenses on the December 31, 2022 consolidated balance sheet. The amounts recorded for clinical trial accruals represent the Company's estimate of the unpaid clinical trial expenses based on the progress of the research and development services for clinical trials compared to the amounts paid for clinical trials through December 31, 2022.

We identified management's estimate of the accruals for clinical trial expenses as a critical audit matter due to the significant management judgement and subjectivity in estimating the accruals. Auditing the Company's clinical trial accruals involved a high degree of subjectivity due to the significant estimation required in determining the progress to completion of specific tasks conducted under the Company's clinical trials and the costs of those tasks that will be invoiced by the vendors, clinical research organizations and consultants and under clinical site agreements subsequent to the date that the financial statements are issued.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding and evaluated the design of controls over management's estimation process, including the process of estimating the expenses incurred to date based on the status of the clinical trials, the significant assumptions about the status of research and development services incurred and the completeness and accuracy of the data used to calculate the estimates. We performed procedures over the clinical trial accruals that included, among others, reading selected agreements and change orders with the vendors, clinical research organizations and consultants, and evaluating the significant assumptions described above and the methods used in developing the clinical trial estimates and calculating the amounts that were unpaid at the balance sheet date. We made direct inquiries of financial and clinical personnel on the status of the clinical trials, progress to completion of clinical trials, method of allocating contractual charges to specific tasks performed during the clinical trials, and the status of change orders. We compared the current estimate of expenses incurred to estimates previously made by management and assessed the historical accuracy of management's previous estimates. We also examined invoices issued and payments made to service providers after the consolidated balance sheet date.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2010.

EISNERAMPER LLP
New York, New York
March 31, 2023

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